

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

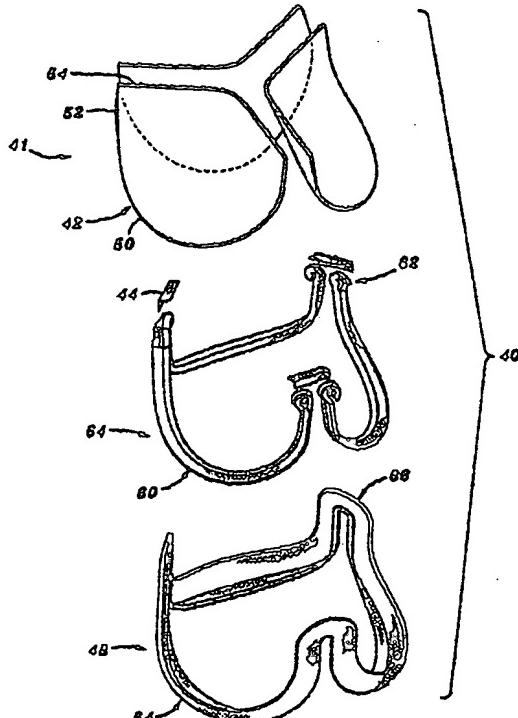
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61F 2/24	A2	(11) International Publication Number: WO 00/42950 (43) International Publication Date: 27 July 2000 (27.07.00)
(21) International Application Number: PCT/US00/01855		(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
(22) International Filing Date: 26 January 2000 (26.01.00)		
(30) Priority Data: · 60/117,445 26 January 1999 (26.01.99) US · 09/332,759 14 June 1999 (14.06.99) US		
(71) Applicant: EDWARDS LIFESCIENCES CORPORATION [US/US]; One Edwards Way, Irvine, CA 92614 (US).		
(72) Inventors: CARPENTIER, Alain, F.; 44, rue Cortambert, F-75016 Paris (FR). SCHRECK, Stefan, G.; 2057 White Birch Drive, Vista, CA 92083 (US). RHEE, Richard, S.; 24344 Darrin Drive, Diamond Bar, CA 91765 (US). NGUYEN-THIEN-NHON, Diana; 1229 West Alton Avenue, Santa Ana, CA 92707 (US). LAM, Hung, LY; 4208 California Avenue, Norco, CA 91760 (US). RECKTENWALD, William; 6201 Torin Drive, Huntington Beach, CA 92647 (US).		
(74) Agents: FARACI, C., Joseph et al.; Edwards Lifesciences LLC, One Edwards Way, Irvine, CA 92614 (US).		

(54) Title: FLEXIBLE HEART VALVE

(57) Abstract

A highly flexible tissue-type heart valve is disclosed having a structural stent in a generally cylindrical configuration with cusps and commissures that are permitted to move radially. The stent commissures are constructed so that the cusps are pivotably or flexibly coupled together at the commissures to permit relative movement therebetween. The stent may be cloth-covered and may be a single element or may be made in three separate elements for a three cusp valve, each element having a cusp portion and two commissure portions; adjacent commissure portions for each pair of adjacent stent element combining to form the stent commissures. If the stent has separate elements their commissure portions may be pivotably or flexibly coupled, or may be designed to completely separate into independent leaflets at bioresorbable couples. The cloth covering may have an outwardly projecting flap that mates with valve leaflets (e.g., pericardial leaflets) along the cusps and commissures. A connecting band may be provided that follows the cusps and commissures and extends outwardly. The valve is connected to the natural tissue along the undulating connecting band using conventional techniques, such as sutures. The connecting band may be a cloth-covered silicon member and attaches to the underside of the valve at the cusps to provide support to the stent and to the outer side of the valve at the commissures. A multi-legged holder is used to implant the valve, with the legs serving to maintain an implant shape to the valve. The holder may have six legs with one releasably connected to each cusp and one releasably connected to each commissure. A method of implantation of the flexible valve using the holder is also disclosed.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

FLEXIBLE HEART VALVE

Field of the Invention

The present invention relates to prosthetic heart valves, and, more
5 particularly, to a prosthetic tissue valve having increased flexibility enabling it
to follow the motions of the annulus and sinus regions.

Background of the Invention

Prosthetic heart valves are used to replace damaged or diseased heart
10 valves. In vertebrate animals, the heart is a hollow muscular organ having four
pumping chambers: the left and right atria and the left and right ventricles, each
provided with its own one-way outflow valve. The natural heart valves are
identified as the aortic, mitral (or bicuspid), tricuspid and pulmonary valves. The
valves of the heart separate chambers therein, and are each mounted in an annulus
15 therebetween. The annuluses comprise dense fibrous rings attached either directly
or indirectly to the atrial and ventricular muscle fibers. Prosthetic heart valves can
be used to replace any of these naturally occurring valves, although repair or
replacement of the aortic or mitral valves are most common because they reside in
the left side of the heart where pressures are the greatest. In a valve replacement
20 operation, the damaged leaflets are excised and the annulus sculpted to receive a
replacement valve.

The four valves separate each ventricle from its associated atrium, or
from the ascending aorta (left ventricle) or pulmonary artery (right ventricle).
After the valve excision, the annulus generally comprises a ledge extending into
25 and defining the orifice between the respective chambers. Prosthetic valves
may attach on the upstream or downstream sides of the annulus ledge, but
outside of the ventricles to avoid interfering with the large contractions therein.
Thus, for example, in the left ventricle a prosthetic valve is positioned on the

inflow side of the mitral valve annulus (in the left atrium), or on the outflow side of the aortic valve annulus (in the ascending aorta).

Two primary types of heart valve replacements or prostheses are known. One is a mechanical-type heart valve that uses a ball and cage arrangement or a pivoting mechanical closure to provide unidirectional blood flow. The other is a tissue-type or "bioprosthetic" valve which is constructed with natural-tissue valve leaflets which function much like a natural human heart valve, imitating the natural action of the flexible heart valve leaflets which seal against each other to ensure the one-way blood flow.

Prosthetic tissue valves comprise a stent having a rigid, annular ring portion and a plurality of upstanding commissures to which an intact xenograft valve or separate leaflets of, for example, bovine pericardium are attached. The entire stent structure is typically cloth-covered and a sewing ring is provided around the periphery for attaching to the natural annulus. Because of the rigidity of the material used in the stent and/or wireform, conventional valves have a diameter that is minimally affected by the natural motion of the heart orifice. In the aortic position, the commissures extend in the downstream direction a spaced distance from the walls of the downstream aortic wall. Movement of the aortic wall or sinuses does not directly affect movement of the cantilevered commissures, though fluid flow and pressures generated by movement of the walls ultimately does cause the commissures to dynamically flex to some extent (i.e., they are cantilevered downstream in the aorta). Because of the inherent rigidity in conventional heart valves, the natural dilatation of the annulus is restricted, imposing an artificial narrowing of the orifice, and increasing the pressure drop therethrough.

Accordingly, there is a need for a more flexible heart valve that responds to the natural motions of the annulus and downstream vessel walls.

Summary of the Invention

The present invention allows the prosthesis to follow the aortic wall motion as well as that of the annulus during systole and diastole phases, thus reducing the loss in pressure caused by restriction of such motions. The 5 solution is a heart valve having a plurality of leaflets, preferably three, directly sutured to the aortic wall, replacing the native valve.

The present invention provides a heart valve including a flexible wireform or stent that allows relative cusp movement or pivoting. The continuous maintenance of leaflet orientation at the commissures provides 10 durability and predictability. Though the leaflets are not wholly independent, they are allowed to move in regions of greatest anatomical motion.

The present invention differs in another respect from bioprosthetic tissue valves of the prior art because it does not include a conventional sewing ring with attendant rigid stent. Alternating peripheral cusps and commissures of the 15 prosthetic valve are attached to the annulus region and the sinus region of the ascending aorta of the host (in the aortic valve version), downstream from the location of the natural leaflets (typically excised).

In accordance with one aspect of the present invention, a prosthetic heart valve is provided including a flexible, generally cylindrical stent having 20 alternating cusps and commissures. A plurality of flexible leaflets is attached to the stent so as to form a one-way valve within the cylinder. A flexible band is attached along the stent and has a free edge extending away from the stent along the alternating cusps and commissures for connecting the heart valve to an anatomical orifice.

25 Another aspect of the present invention is a highly flexible heart valve including a stent/leaflet subassembly having a peripheral stent and a plurality of leaflets disposed therewithin. The stent/leaflet subassembly defines alternating cusps and the commissures. A connecting band is attached to the stent/leaflet

subassembly and follows the alternating cusps and commissures. The band includes a free edge extending from the stent for connecting the heart valve to an anatomical orifice.

In a still further aspect of present invention, a prosthetic heart valve 5 comprises a plurality of flexible leaflets, each having an arcuate cusp edge and a coapting edge. The heart valve includes a stent with a plurality of cusps connected to each other at upstanding commissures to generally define a substantially cylindrical volume therebetween. The leaflets are attached to the stent within the cylindrical volume and the cusps are free to move with respect 10 to one another about the commissures.

In another embodiment, the present invention provides a prosthetic heart valve comprising a stent having a plurality of stent members adjacently disposed generally around a circle to define a substantially cylindrical volume therebetween. The stent includes a plurality of alternating cusps and 15 commissures. Preferably, the stent members each have a cusp and two commissure regions, with adjacent commissure regions of the stent members together defining each of the commissures of the stent. The stent members may be coupled together to pivot or flexibly move with respect to one another. The coupling may be permanent, or may comprise a bio-resorbable structure that 20 permits the stent members and associated leaflets to move independently from one another.

A further aspect of the invention is a heart valve having three leaflets which are directly sutured to the aortic wall, replacing the native valve. In one embodiment, the commissures of adjacent cusps may be connected during 25 implant, and can become independent thereafter. This gives the cusps and commissures freedom to move during systole and diastole, thus improving the pressure gradient. To facilitate implantation, the commissures may be initially temporarily connected, such as with a biodegradable material. In a minimally

invasive contexts, the valve may be partially collapsible to facilitate delivery through a narrow channel to the implantation site.

Alternatively, the invention provides a reduced pressure gradient prosthetic heart valve that has multiple, preferably three, totally or partially independent leaflets. The leaflets are directly sutured to the aortic wall, replacing the native valve. The commissures of adjacent leaflets may be connected during implant and become independent thereafter, or they may be linked together at the commissure. For example, adjacent commissures may be linked by fasteners that are either unique to each leaflet (a commissure clip or a clip in conjunction with a cusp support), or comprise a continuous scalloped wire or frame around all of the leaflets. The fastener must be sufficiently flexible to preserve the motion of the three leaflets during systole. Because of the independent (or flexibly coupled) nature of the leaflets, the commissures are free to move during the systole/diastole cycle, and the pressure gradient through the valve is therefore significantly reduced.

Still further, the invention contemplates the replacement of a single leaflet with an independent prosthetic leaflet, while the other native leaflets remain and are still functional. That is, if one native leaflet is not functioning because of disease or other condition, the entire valve need not be replaced, just the damaged leaflet. The present invention thus enables a less invasive procedure that obviates the removal of healthy leaflets. Still further, a minimally-invasive implantation device may be used to deliver and implant the independent leaflet(s).

Desirably, the stent of the prosthetic heart valve of the present invention is configured to permit the cusps and commissures to move radially in and out. In one embodiment, the stent comprises a cloth covered rod-like structure. The cloth covering closely surrounds the stent and includes a flap projecting therefrom substantially the entire length of the cusps and commissures for

connecting the stent to both the flexible band and the leaflets. The band preferably comprises a suture-permeable inner member, such as silicone, covered by cloth. The cusps of the stent may be pivotally or flexibly coupled to each other at the commissures. Preferably, the stent comprises separate cloth-covered stent members that each define a cusp region and two commissure regions, adjacent commissure regions of the stent members together defining each of the commissures of the stent. The commissure regions of the separate stent members desirably remain spaced apart, with the leaflets extending therethrough to be attached between the cloth covering and the outer connecting band. In this manner, the leaflets are connected to separate stent members, and not to each other to facilitate flexing of the valve.

In another aspect of the present invention, a holder is provided for mounting the flexible heart valve. The holder includes a central hub with a plurality of radially outward upper legs, and a plurality of lower legs angled downward and outward. The upper and lower legs are adapted to connect to the alternating cusps and commissures of a flexible valve so as to maintain the position of the valve during implantation.

The present invention further provides a combination of a flexible prosthetic heart valve and a rigid holder. The flexible heart valve includes alternating cusps and commissures in a generally cylindrical configuration adapted to move radially in and out with respect to one another. The holder includes structure for maintaining a fixed shape of the flexible prosthetic heart valve during implantation.

In a still further aspect of the present invention, a heart valve leaflet is provided comprising a flexible, planar body having an arcuate cusp edge terminating at outer tips. The planar body includes a coapting edge that is defined by two relatively angled lines joined at an apex directed away from the cusp edge midway between the two tips. Desirably, the leaflet is made of

pericardial tissue.

The present invention further provides a method of implantation of a heart valve, including the steps of: providing a flexible heart valve having alternating cusps and commissures in a generally cylindrical configuration and adapted to move radially in out with respect to one another; attaching a holder to the valve that restricts relative movement of the cusps and commissures; positioning the heart valve in proximity to an anatomical orifice; implanting the heart valve; and, disconnecting the holder from heart valve.

10

Brief Description of the Drawings

Figure 1 is a sectional view through the left half of a human heart showing a systolic phase of left ventricular contraction;

Figure 2 is a sectional view through the left half of a human heart showing a diastolic phase of left ventricular expansion;

15

Figure 3 is an exploded perspective view illustrating sub-assemblies of a prosthetic heart valve of the present invention;

Figure 4A is a top plan view of an internal stent of the prosthetic heart valve of the present invention;

Figure 4B is an elevational view of the internal stent of Figure 4A;

20

Figure 5 is an elevational view of a stent assembly of the prosthetic heart valve;

Figures 6A and 6B are sectional views through two locations of the stent assembly, taken along lines 6A-6A and 6B-6B of Figure 5;

Figures 7A, 7B, and 7C are plan views of leaflets suitable for use in the prosthetic heart valve of the present invention;

Figure 8 is an exploded perspective view of a stent/leaflet sub-assembly and a connecting band of the prosthetic heart valve of the present invention;

Figure 9 is an elevational view of an inner member of the connecting

band;

Figure 10 is a cross-sectional view through a cusp of the connecting band shown in Figure 8;

Figure 11 is a perspective view of an assembled prosthetic heart valve of the present invention;

Figure 12A is a cross-sectional view through a cusp region of the prosthetic heart valve of the present invention, taken along line 12A-12A of Figure 11, and showing a portion of the host annulus in phantom;

Figure 12B is a cross-sectional view through a commissure region of the prosthetic heart valve of the present invention, taken along line 12B-12B of Figure 11, and showing a portion of the host aortic wall in phantom;

Figure 13 is a schematic view showing relative movement of the aortic and annulus walls during systolic flow;

Figure 14A is a plan view of only the stent members of the prosthetic valve flexed in accordance with the anatomical motions during systole shown in Figure 13;

Figure 14B is an elevational view of the stent members flexed in accordance with the anatomical motions during systole shown in Figure 13;

Figure 15 is a schematic view showing relative movement of the aortic and annulus walls during diastolic flow;

Figure 16A is a plan view of only the stent members of the prosthetic valve flexed in accordance with the anatomical motions during diastole shown in Figure 15;

Figure 16B is an elevational view of the stent members flexed in accordance with the anatomical motions during diastole shown in Figure 15;

Figure 17 is a perspective view of an alternative stent assembly for use in a prosthetic heart valve in accordance with the present invention;

Figure 18 is a perspective view of an internal stent of the stent assembly

of Figure 17;

Figure 19 is an exploded view of a commissure tip region of the stent assembly of Figure 17;

Figures 20A-20E are elevational views of alternative stents for use in a prosthetic heart valve in accordance with the present invention;

Figure 21 is a detailed view of a commissure region of the alternative stent of Figure 20E;

Figure 22 is a detailed view of a commissure region of a still further alternative stent accordance with the present invention;

Figure 23 is an exploded perspective view of the prosthetic heart valve of the present invention and a holder used during implantation of the valve;

Figure 24 is a perspective view of the holder coupled to the valve;

Figure 25 is a top plan view of the holder coupled to the valve;

Figure 26 is a cross-sectional view through the holder and valve, taken along line 26-26 of Figure 25;

Figures 27A and 27B are perspective views of an alternative holder for the prosthetic heart valve of the present invention used during implantation of the valve;

Figure 28A is a perspective exploded view of an independent leaflet for use with other such leaflets that are attached directly to an ascending aorta and function together as a prosthetic valve;

Figure 28B is a perspective assembled view of the independent leaflet of Figure 28A;

Figure 29A is an elevational view of one embodiment of an attachment structure between two of the adjacent independent leaflets of Figure 28B;

Figure 29B is an elevational view of a continuous structure for attaching the independent leaflets of Figure 28B;

Figure 30 is a perspective view of an exemplary device for measuring

the native tissue prior to select the appropriate sized independent leaflet of
Figure 28B for implantation;

Figures 31A-31C are schematic views of a device for automatically
implanting an independent leaflet of the present invention, illustrating a
5 collapsible articulated holder especially suited for minimally invasive
environments;

Figures 32A-32C are schematic views of a further device for
automatically implanting an independent leaflet of the present invention,
illustrating a multi-part holder for installing attachment staples; and

10 Figure 33 is a cross-sectional view through one embodiment of an
attachment structure for the independent leaflet embodiment, or for multi-leaflet
embodiments for that matter.

Description of the Preferred Embodiments

15 The present invention provides a highly flexible aortic heart valve that is
attached generally along a scalloped or undulating perimeter downstream from
where the natural leaflets were originally attached. The natural leaflets include
arcuate cusp portions separated by common commissure portions. If the natural
valve has three leaflets, and has a vertically oriented flow axis, the leaflets are
20 evenly distributed circumferentially 120° apart with lower cusp portions and
upstanding commissure portions. The commissure portions are connected
between the cusp portions and are generally axially aligned along the aortic
wall. The annular root of an aortic valve is composed of fibrous tissue and
generally conforms to the undulating perimeter of the valve to support the
leaflets. In this respect, implanting the aortic heart valve of the present
25 invention involves excising the natural leaflets and attaching the prosthetic heart
valve proximate the fibrous annulus, but also in part up the aortic wall. Because
of the particular construction of the present heart valve, as will be described

below, the attachment means, be it sutures, staples, adhesives, or otherwise, may be anchored into the aortic wall itself, adjacent to the fibrous annulus.

Anatomy

5 To better illustrate the advantages of the flexible heart valve of the present invention, an understanding of the movement of the annulus and aorta is helpful. In this regard, Figures 1 and 2 illustrate the two phases of left ventricular function; systole and diastole. Systole refers to the pumping phase of the left ventricle, while diastole refers to the resting or filling phase. Figures 10 1 and 2 illustrate in cross section the left chamber of the heart with the left ventricle 20 at the bottom, and the ascending aorta 22 and left atrium 24 diverging upward from the ventricle to the left and right, respectively. Figure 1 illustrates systole with the left ventricle 20 contracting, while Figure 2 illustrates diastole with the left ventricle dilating. The aortic valve 28 is 15 schematically illustrated here as having leaflets 30. Contraction of the ventricle 20 causes the mitral valve 26 to close and the aortic valve 28 to open, and ejects blood through the ascending aorta 22 to the body's circulatory system, as indicated in Figure 1 by the arrows 32. Dilation of the ventricle 20 causes the aortic valves 28 to close and mitral valve 26 to open, and draws blood into the 20 ventricle from the left atrium 24, as indicated in Figure 2 by the arrows 33.

The walls of the left chamber of the heart around the aortic valve can be generally termed the annulus region 34 and the sinus region 36. The annulus region 34 generally defines an orifice that is the narrowest portion between the ventricle 20 and ascending aorta 22, which as noted above is composed of 25 generally fibrous tissue. The sinus region 36 is that area just downstream from the annulus region 34 and includes somewhat elastic, less fibrous tissue. Specifically, the sinus region 36 typically includes three identifiable, generally concave sinuses (formally known as Sinuses of Valsalva) in the aortic wall

intermediate the upstanding commissures of the valve 28. The sinuses are relatively elastic and are constrained by the intermediate, more fibrous commissures of the aortic annulus. Those of skill in the art will understand that the annulus region 34 and sinus region 36 are not discretely separated into either 5 fibrous or elastic tissue, as the fibrous commissures of the annulus extend into the sinus region 36.

The sinuses tend to move in and out to facilitate fluid dynamics of the blood in conjunction with systole and diastole. During systole, as seen in Figure 1, the sinus region 36 expands somewhat to a diameter A. This 10 facilitates blood flow through the ascending aorta 22 to the rest of the body. In contrast, during the diastolic phase as seen in Figure 2, the sinus region 36 contracts somewhat to a smaller diameter B. The diameters A and B are intended to be a measurement of the radial movement of the commissure regions of the valve 28. In this regard it will be understood that the cross-sections shown are not taken in a single plane, but instead are taken along two 15 planes angled apart 120° with respect one another and meeting at the midpoint of the aorta 22. The sinus region 36 has a neutral, or relaxed diameter (not shown) somewhere in between diameters A and B.

The annular region 34 also moves in and out during the systolic and 20 diastolic phases: As seen in Figure 1, the annular region 34 contracts somewhat to a diameter C during systole. In contrast, during the diastolic phase as seen in Figure 2, the annular region 34 expands somewhat to a larger diameter D. Much like the sinus region 36, the annular region 34 has a neutral, or relaxed 25 diameter (not shown) somewhere in between diameters C and D.

As will be explained more fully below, the prosthetic valve of the present invention accommodates the in and out movements of both the annular region 34 and the sinus region 36. That is, alternating peripheral portions of the prosthetic valve are attached to the annular region 34 and the sinus region 36

and move accordingly. It is important to point out that the preceding discussion of dynamic movement of the annulus and sinus regions is based on preliminary understanding of such movement. That is, direct measurements of these movements are problematic, and thus certain assumptions and predictions must be made. The actual dynamic movement in any particular human heart may be different, but the principles of the present invention would still apply. That is, relative movement in the annulus and sinus regions during systole and diastole does exist, and the flexible prosthetic heart valve of the present invention can accommodate any such movement.

10

Valve Subassemblies

With reference now to Figure 3, the primary sub-assemblies of a preferred embodiment of the prosthetic heart valve 40 of the present invention are shown in exploded view. For purposes of discussion, the directions up and down, upper and lower, or top and bottom, are used with reference to Figure 3, but of course the valve can be oriented in any direction both prior to and after implantation. From top to bottom, the heart valve 40 comprises a group 41 of three leaflets 42, three angled alignment brackets 44, a stent assembly 46, and a connecting band 48. Each of the sub-assemblies seen in Figure 3 is procured and assembled separately (except for the group of leaflets, as will be explained), and then joined with the other sub-assemblies to form the fully assembled valve 40 as seen in Figure 11.

The prosthetic valve 40 is a trifoliate valve with three leaflets 42. Although three leaflets are preferred, and mimic the natural aortic valve, the principles of the present invention can be applied to the construction of a prosthetic valve with two or more leaflets, depending on the need.

Each of the sub-assemblies seen in Figure 3 include three cusps separated by three commissures. The leaflets 42 each include an arcuate lower

cusp edge 50 terminating in upstanding commissure regions 52. Each leaflet 42 includes a coapting or free edge 54 opposite the cusp edge 50. In the assembled valve 40, the cusp edges 50 and commissure regions 52 are secured around the periphery of the valve, with the free edges 54 permitted to meet or "coapt" in the middle. The stent assembly 46 also includes three cusps 60 separated by three upstanding commissures 62. In like manner, the connecting band 48 includes three cusp portions 64 separated by three upstanding commissure portions 66. Each of the sub-assemblies will now be described in detail.

10 Stent Assembly

Various components of a preferred stent assembly 46 are seen in Figures 4-6. The stent assembly 46 comprises an inner stent 70 and an outer cloth cover 72. More specifically, the inner stent 70 desirably includes three identical and separate stent members 74, each of which has a separate cloth covering. As seen best in Figure 4B, each stent member 74 comprises an arcuate lower cusp region 76 and upstanding commissure regions 78 each terminating at a tip 80. The stent members 74 comprise elongate rods or wires, preferably made out of an elastic biocompatible metal and/or plastic alloy, such as Elgiloy®, Nitinol, polypropylene, etc.. The material selected for stent members 74 should be elastic to permit flexing along their lengths, but should possess a relatively high modulus of elasticity to avoid asymmetric deformation of the constructed valve 40. The stent 70 supplies an inner frame for the valve 40 that is relatively more rigid than the other components. Therefore, the stent 70 acts to limit total flexibility of the valve 40.

25 The stent members 74 are desirably bent into the illustrated shape, using conventional wire-forming techniques. Each of the stent members 74 is identical, and terminates in the tips 80 which are bent inward with respect to the arcuate cusp regions 76 to nearly form closed circles. As is seen in Figure 4B, a

gradual radially outward bend 82 (with respect to the cylindrical stent 70) is provided in the stent members 74 at a transition between each of the commissure regions 78 and the intermediate cusp region 76. This bend 82 permits each of the stent members 74 to remain in a circular configuration, as seen from above in Figure 4A. That is, if the cusp regions 76 extended in a plane between each of the commissure regions 78, the plan view would be somewhat triangular. Instead, each of the cusp regions 76 includes a lower apex 84, and the apices of all of the cusps define a circle concentric with and having the same diameter as a circle defined by all of the tips 80. The stent 70 thus defines a substantially cylindrical volume therewithin. Of course, other volumes may be defined by the stent 70 wherein the tips 80 define a circle that is smaller or larger than a circle defined by the apices 84. For example, the apices 84 may be provided outward from the tips 80 so the stent 70 defines a frusto-conical volume therewithin.

As seen in Figure 5, each of the stent members 74 is preferably covered with a generally tubular cloth 72 from tip to tip 80. The cloth cover 72 is a biocompatible fabric, such as polyterephthalate, and has a varying cross sectional shape, as indicated in Figures 6A and 6B. More specifically, the cloth cover 72 includes a tubular portion closely conforming around each of the stent members 74 and a flap 86 extending radially outward from the stent member (with respect to the curvature of the cusp regions 76). The cloth cover 72 is formed by wrapping an elongated sheet of fabric around each of the stent members 74 and joining the free edges with sutures 88 to form the flaps 86. As seen in Figure 5, the flap 86 extends from each stent member 74 in a direction that is generally outward with respect to the cusp region 76, and continues in the same general orientation up the commissure regions 78 to the tips 80. The flap 86 has a dimension that is longest at the apex 84 of each cusp region 76 and shortest at the tips 80. Indeed, the flap 86 is preferably nonexistent at the tips

80, and gradually increases in size from the tip 80 to the apex 84. Therefore, the cross-section of Figure 6A taken through the commissure region 78 shows the flap 86 having a small dimension d1, and the cross-section of Figure 6B taken through the apex 84 shows the flap 86 having a longer dimension d2.

- 5 The final component of the stent assembly 46 is an attachment means 90 for joining each of a cloth-covered stent members 74. Preferably, the attachment means 90 comprises threads or sutures sewn through the central holes in each of the circular tips 80, as shown in Figure 5, although other suitable attachment means could be used, such as rings, cinches, or the like.
- 10 The attachment means 90 may be wrapped around or sewn through the cloth cover 72. In joining the tips 80, the attachment means 90 are desirably not wrapped extremely tightly, but are instead provided with some slack to permit relative movement of the tips, as will be described below. When the stent members 74 are attached, as seen in Figure 5, the stent 70 exhibits three cusps
- 15 corresponding to the cusp region 76 of each member, and three upstanding commissures defined by the juxtaposition of adjacent pairs of commissure regions 78.

In a preferred embodiment of the present invention the attachment means 90 comprises a non-bioresorbable material to ensure that the individual stent members 74 are maintained in the shape of the stent 70. In an alternative configuration, however, the attachment means 90 comprises a bioresorbable material that dissolves over a period of time after implantation. In such an embodiment, the natural host tissues may have grown in and around the porous portions of the valve 40 to help retain the original shape of the stent 70. In some instance, however, very little tissue overgrowth may have occurred prior to the attachment means 90 dissolving, and the individual stent members 74 are permitted to move radially a great deal with respect to one another. In the latter embodiment, wherein the stent members 74 are permitted to spread apart, the

connecting band 48 may be re-configured to be non-continuous at the commissure portions 66 (see Figure 3). As a consequence, each individual stent member 74 and associated leaflet 72 moves entirely independently of the others, albeit all oscillating with the natural contractions and expansions of the surrounding aortic wall. Such independent leaflet movement may greatly reduce any potential pressure drop across the valve. Although one embodiment is to provide a bioresorbable attachment means 90 such as the sutures shown in the embodiment of Figure 5, those of skill in the art will understand that any of the coupling means connecting the individual stent members 74 disclosed in the present application could be modified to resorb over time.

The stent assembly 46 provides an inner support frame that is generally rigid along any one of stent members 74, but which permits the stent members to move with respect to one another. In this context, "generally rigid" refers to the structural strength of the stent members 74 that is sufficient to maintain the general shape of the stent 70, but that permits some flexing along the length of the stent members. Though the stent members 74 are generally rigid, they are able to move with respect to one another. More particularly, joining the stent members 74 with the attachment means 90 creates nodes or pivot points of the valve 40 at the commissures 62 of the stent assembly 46. As will be more fully explained below with reference to Figures 13-16, the stent members 74 are permitted to pivot with respect to one another as they move radially inward and outward. Inward pivoting is permitted by spaces 94, seen in Figure 5, defined between adjacent cloth-covered commissure regions 78 of each stent member 74. These regions 94 are generally triangular and gradually increase in size from the attached commissure tips to the diverging cusps.

Leaflet Configurations

Figures 7A, 7B, and 7C are plan views of various configurations of

leaflets 42 suitable for use in the prosthetic heart valve 40. Figure 7A shows a leaflet 42 having the aforementioned cusp 50, commissure regions 52, and free edge 54. It will be noted that the coapting edge 54 comprises two linear portions extending from an apex 100 to outer tips 102. The two portions of the free edge 54 are angled with respect to one another and define sides of a triangular region 104 having as its hypotenuse an imaginary line 106 extending between the opposed tips 102. The triangular region 104 of each leaflet 42 is under less tension during dynamic motion of the valve 40, and helps ensure coaptation of the leaflets. That is, the leaflets 42 are generally secured along the cusp 50 and commissure regions 52, and thus the majority of each leaflet 42 is placed in stress except in the region above imaginary line 106. In this regard, an imaginary (dashed) fold line 108 defines an outer margin 110 of the leaflet 42 that is used to secure the leaflets into the valve 40. As will be clear from the discussion below, the margins 110 are sutured between the stent assembly 46 and connecting band 48 (Figure 3), and the free edge 54 of the leaflet extends across the cylindrical region defined within the valve 40, and is generally free to move in that region. Because the triangular leaflet region 104 is relatively stress-free, it tends to roll over under the influence of fluid dynamic forces, thus helping the three leaflets to coapt and prevent valve insufficiency.

Figure 7B shows a leaflet 112 that is substantially the same as the leaflet 42 of Figure 7A, and thus like elements will be given the same numbers. The leaflet 112 includes a pair of generally triangular shaped commissure tabs 114 in the commissure regions 52. The tips 102 are thus spaced farther apart than in the version shown in Figure 7A. The commissure tabs 114 are used to more securely fasten each of the leaflets to the commissures 62 of the stent assembly 46 (Figure 3). The cloth cover 72 of the stent assembly 46 includes a flap 86 (Figure 5) which diminishes in size in the commissure regions. The tabs 114 are thus wrapped farther around the cloth-covered stent assembly 46 in the

commissure regions and sutured thereto, thus facilitating a more durable connection.

Figure 7C is a further variation of a leaflet 116 which is, again, the same in all respects to the leaflets described above, except for somewhat trapezoidal-shaped commissure tabs 118. Again, the commissure tabs 118 help to secure the leaflets 116 in the prosthetic valve 40.

Stent/Leaflet Sub-Assembly

Figure 8 illustrates a stent/leaflet sub-assembly 120 in which the leaflets 42 are secured to the stent assembly 46. Preferably, leaflets 42 are pre-attached to align the free edges 54. In this manner, the free edges 54 of each two adjacent leaflets 42 extend outward in juxtaposition and are received within the triangular space 94 defined between the commissure regions 78 of the stent assembly 46 (Figure 5). The group of leaflets 41 is thus "inserted" underneath the stent assembly 46 until the juxtaposed free edges 54 of the leaflets 42 are in close proximity below the attachment means 90. The outer margin 110 of each leaflet 42 is folded underneath the corresponding cusp 60 of the stent assembly 46. At this point, sutures or other such means attach the margins 110 to the flap 86 of the stent assembly 46. The leaflets 42 can remain attached to one another at their adjacent tips 102 (or along the free edges 54 near the tips), or can be separated for maximum valve flexibility or when the stent is designed to separate into individual stent members by bio-resorption of a commissure couple.

If either the leaflet 112 or leaflet 116 of Figure 7B or 7C are used, the respective commissure tabs 114 or 118 are wrapped around the adjacent part of the stent assembly 46 and secured thereto. In a preferred assembly method, the leaflets 42 are simply retained in position with respect to the stent assembly 46 with temporary sutures or other such means, to permit the stent/leaflet

subassembly 120 to be finally joined together with the connecting band 48 of Figure 8.

Figure 8 also illustrates the three alignment brackets 44 and that each has a generally L-shaped cross-section and comprises a cloth-covered inner member (not separately numbered). The inner member preferably has minimum elasticity, but is relatively thin and lightweight. One preferred material for the inner member is a polyester film such as Mylar®. The brackets 44 are preferably joined to the valve 40 at the time the stent/leaflet sub-assembly 120 and connecting band 48 are joined, and thus will be described more fully below with respect to Figure 11.

Connecting Band

Figures 9 and 10 illustrate the connecting band 48 in more detail, comprising an inner member 130 surrounded by a cloth cover 132. As mentioned previously with respect to Figure 3, the connecting band 48 includes three cusp portions 64 alternating with commissure portions 66, all generally formed in a tubular configuration. This shape is provided by the inner member 130, with the cloth cover 132 simply draped and sewn thereover. In a preferred embodiment, the inner member 130 is molded of silicone rubber, and the cloth cover 132 is polyterephthalate.

The inner member 130 has a varying cross sectional shape along the cusps and commissures. Figure 10 is cross-section through one of the cusp portions 64 of the connecting band 48, and shows a region of the inner member 130 having an inner ledge 134 and upwardly angled outer free margin 136. The cloth-covered ledges 134 extend generally radially and define three stent support regions 138 of the connecting band 48, as seen in Figure 8. The ledge 134 has its greatest radial dimension at the midpoint of each of the cusp portions 64 and gradually tapers down in size toward the commissure portions 66.

Likewise, the free margins 136 form their greatest outward angle with respect to a central axis of the connecting band 48 at each cusp portion 64, and gradually re-align to be parallel to the central axis in the commissure portions 66. The cross-section of the inner member 130 at the commissure portions 66 is seen in 5 Figure 12B. A series of triangular shaped ribs 140 projects outward from the inner member 130. The ribs 140 are formed around the entire inner member 130, along both the cusp and commissure regions. As seen in Figure 8, the commissure portions 66 of the connecting band 48 define generally axial gaps 142 that help permit flexing of the valve 40. It should be noted that the 10 connecting band 48 may be discontinuous at the commissure portions 66 if the valve has bioresorbable commissures and is designed to separate into individual "leaflets."

Assembled Valve

Figure 11 illustrates the assembled valve 40 in perspective, while 15 Figures 12A and 12B show cross-sections through a valve cusp 150 and valve commissure 152, respectively. The connecting band 48 is sewn or otherwise attached to the exterior of the stent/leaflet subassembly 120. Actually, as seen in Figure 12A, the connecting band 48 is attached underneath the stent/leaflet 20 subassembly 120 in the cusp 150, but the free margins 136 of the connecting band are positioned to the outside of the subassembly. In addition, the alignment brackets 44 are installed with a vertical leg 156 interposed between the commissures 62 of the stent assembly 46 and the commissure portions 66 (Figure 3) of the connecting band 48. A horizontal leg 154 of each of the 25 alignment brackets 44 projects radially inward to cover the tips 80 of the stent assembly 46. The alignment brackets 44 help hold each two adjacent tips 80 of the three-piece stent 70 together, especially helping to prevent radial misalignment. The brackets also provide flat surfaces which a holder can contact,

as seen best in Figure 26.

With reference to the cross-section of Figure 12A, the sandwiched configuration of the stent assembly 46, leaflet 42, and connecting band 48 can be seen. More specifically, the cloth flap 86 of the stent assembly 46 aligns with the leaflet margins 110, which in turn rest on the stent supports 138. A series of suture stitches 158 are used to secure these elements together. Preferably, the flap 86 terminates at the same location as the margin 110 of each leaflet 42, and at the corner defined in the connecting band 48 between each ledge 134 and free margin 136. The radially innermost wall of the ledge 134 is preferably inward from the stent member 74. This construction helps prevent the stent 70 from migrating downward with respect to the connecting band 48.

The host annulus 162 is seen in phantom with the aortic wall 164 continuing upward therefrom. It can be readily seen that the angled shape of the cusp portions 64 of the connecting band 48 conform nicely to the host annulus region. The triangular ribs 140 provide volume at the free margins 136 of the connecting band 48 to facilitate connection to the natural tissue; in other words, more volume provides more of a "bite" for the surgeon to secure the band 48 with a suture needle. Although the conventional means for attaching the valve 40 to the host tissue is with sutures, which are not shown, the present invention should not be construed as limited to being implanted with sutures and other means such as staples, adhesives, and the like could be used.

Now with reference to Figure 12B, the assembly of the valve components in the commissure region is seen. The commissure edges 52 of each of the leaflets 42 are sandwiched in between the stent assembly 46 and connecting band 48. More particularly, the commissure edges 52 are sandwiched between the flaps 86 and the generally planar commissure portions 66 of the connecting band 48 (Figure 8). Sutures 170 are provided to join these elements together. Again, the commissure edges 52 preferably terminate at the

same location as the flaps 86. Figure 12B also illustrates the gap 142 provided in the commissure regions of the connecting band 48, and the lack of structural connection between the two sides of each valve commissure 152.

Figure 12B shows in phantom a portion of the aortic wall 172 to which
5 the commissures 152 of the valve 40 are attached. Again, the particular attachment means is not shown, but the connecting band 48 is traditionally sutured to the wall 172.

Dynamic Motion of the Prosthetic Heart Valve

10 Figures 13 and 15 illustrate a conduit portion of a heart in the region of the aortic valve and relative motions of the conduit walls during systole and diastole, respectively. In particular, Figure 13 shows an open valve 200 and systolic blood flow 202, while Figure 15 shows a closed valve 204 and diastolic back flow of blood 206. As described with respect to Figures 1 and 2, the
15 regions around the aortic valve can be generally separated into an annulus region 208 and a sinus region 210.

As mentioned previously, the annulus region 208 is expected to contract during the systolic phase, as indicated by the arrows 212 in Figure 13, and expand during the diastolic phase, as indicated by the arrows 214 in Figure 15.
20 Conversely, the sinus region 210 is expected to expand during the systolic phase, as indicated by the arrows 216 in Figure 13, and is expected to contract during the diastolic phase, as indicated by the arrows 218 in Figure 15. The movements of the conduit walls are shown with respect to a neutral or relaxed position 220, and may be exaggerated from the true movements. Also, as
25 mentioned above, these movements are educated guesses and may be different for some, if not most patients. However, the flexible heart valve of the present invention accommodates all variations of such movements.

Figures 14 and 16 schematically illustrate the synchronous movement of

the prosthetic valve 40 of the present invention with respect to the movements of the host tissue in systolic and diastolic phases as seen in Figures 13 and 15. To simplify this explanation, Figures 14 and 16 only illustrate the stent 70 of the present invention, which as previously described acts as a limitation to movement of the entire valve 40 and fairly represents movement of the entire valve.

With reference to Figures 14A and 14B, during systole the valve experiences outward commissure movement, as indicated by the arrows 230. At the same time, the valve experiences inward movement at the cusps, as indicated by the arrows 232. During diastole, in contrast, and as seen in Figures 16A and 16B, the valve experiences inward commissure movement, as indicated by the arrows 234. At the same time, the valve experiences outward movement at the cusps, as indicated by the arrows 236.

15 Alternative Stents

Figures 17-19 illustrate an alternative stent assembly 250 comprising an inner stent 252 and an outer cloth cover 254. As with the earlier stent assembly 46, the stent assembly 250 includes alternating cusps 256 and commissures 258. As best seen in Figure 18, the stent 252 includes three separate stent members 260 having arcuate commissure tips 262 that are curved toward one another. A generally disk-shaped commissure housing 264 encompasses the adjacent commissure tips 262, retaining the stent members 260 together while permitting relative pivoting.

Figure 19 illustrates two adjacent commissure tips 262 and the commissure housing 264 exploded into a male housing portion 266 and a female housing portion 268. The housing portions are so named because they are joined together through interference between a button 270 of the male housing portion 266 and an aperture 272 on the female housing portion 268.

Each portion of the commissure housing 264 includes a circular groove 274 for receiving the arcuate tips 262. The grooves 274 combined to form a circular channel having an axis 276 within which the arcuate tips 262 are received and can slide. When assembled together, the commissure housings 264 thus provide 5 nodes of rotation for each of the stent members 260.

Figure 20A illustrates an alternative stent 280 suitable for use in a heart valve of the present invention. The stent 280 includes three stent members 282, each having commissures with a flex region 284 and tips 286. The tips 286 of adjacent stent members 282 are secured together by sutures or other suitable 10 means (not shown). The flex regions 284 comprise sections of each stent member 282 which are bent away from each other. The stent members 282 can thus pivot with respect to one another about the connected tips 286. Upon inward movement of the stent members 282, a fulcrum 288 is created by interaction between the stent members at the lower end of the flex region 284. 15 The relative flexibility in inward or outward movement of the stent members 282 can be modified by selection of the cross sectional size and shape of the stent members, and overall configuration of the flex region 284.

Figure 20B illustrates a second alternative stent 290 suitable for use in a heart valve of the present invention. The stent 290 includes three wires 292 and 20 has commissure regions 294 formed by bent ends of the wires and a junction member 296. In this embodiment, the junction member 296 either rigidly holds the terminal ends of each of the wires 292, or permits the wires to slide or otherwise flex with respect to one another. If the wires are rigidly attached to the junction member 296 the shape of the wires in the commissure region 294 25 reduces stress risers in bending.

Figure 20C illustrates a third alternative stent 300 suitable for use in a heart valve of the present invention. The stent 300 comprising three separate wires 302 terminating at circular commissure tips 304. Each of the commissure

tips 304 is rotatably fastened around a pin 306 provided on a junction plate 308 common to adjacent wires 302. In this manner, the tips 304 remained located close to one another, while the cusps of the wires 302 can pivot in and out.

5 Figure 20D illustrates a fourth alternative stent 310 suitable for use in a heart valve of the present invention. The stent 310 is made in one piece with a series of alternating cusps 312 and commissures 314. The commissures 314 comprising a nearly 360° bend in the stent 310 which permits each cusp 312 to easily flex with respect to the other cusps.

10 Figure 20E illustrates a fifth alternative stent 320 suitable for use in a heart valve of the present invention. The stent 320 comprises three wire-like stent members 322, adjacent ones of which are joined together at commissure regions 324 by a U-shaped coupling 326 and a pair flexible sleeves 328. Figure 21 is a detail of one of the commissure regions 324 showing in hidden lines the adjacent ends of the coupling 326 and stent members 322. The couplings 326 are preferably sized with the same diameter as the stent members 322, and the sleeves 328 are tubular with a constant diameter lumen. The sleeves 328 may be made of silicone, or a flexible polymer such as polyurethane or the like. Other flexible interfaces such as sleeves 328 are contemplated, such as, for example, a single block of silicone into which the commissure regions 324 of 15 the stent members 322 are molded.

20 Figure 22 is a detailed view of a commissure region 330 of a still further alternative stent suitable for use in a heart valve of the present invention. The stent is made in one piece with adjacent cusps 332 being joined by a coil spring tip 334. Again, great flexibility is provided by the coil spring tips 334 to enable relative motion of the cusps 332. The amount of flexibility is selected as in any 25 spring by varying the material, cross-sectional size and shape, and number of turns of the spring.

Valve Holder

Figures 23-26 illustrate a preferred holder 350 useful for implanting the flexible heart valve 40 of the present invention. As the heart valve 40 is relatively flexible, the holder 350 must provide adequate support to insure a stable platform for the surgeon to position the valve for attachment to the natural tissue. In other words, because the flexible prosthetic heart valve 40 of the present invention exhibits alternating cusps and commissures in a generally cylindrical configuration that are adapted to move radially in and out with respect to one another, the holder 350 desirably provides rigid structure for maintaining a fixed shape of the valve during implantation. In addition, the holder 350 must include structure to allow quick release from the valve 48 after the valve is implanted.

As seen in Figure 23, the holder 350 comprises a proximal handle socket 352 having an inner bore 354 for receiving the distal end of a handle (not shown). The socket 352 may be provided with internal threads, or other such quick-release coupling structure to facilitate handle connection and disconnection. The holder 350 has three radially outwardly-directed commissure legs 356, and three outwardly and downwardly angled cusp legs 358. Consistent with the distribution of the cusps 150 and commissures 152 of the valve 40, the commissure legs 356 are oriented 120° apart, and the cusp legs 358 are oriented 120° apart, with the three commissure legs being offset with respect to the three cusp legs by 60°.

As seen in Figure 24, each of the commissure legs 356 extends outward from the handle socket 352 into proximity with one of the valve commissures 152 and is secured thereto with an upper suture 360. Likewise, each of the cusp legs 358 extends outward and downward from the handle socket 352 into proximity with a midpoint of one of the valve cusps 150, and is secured thereto with a lower suture 362. The lower end of each cusp leg 358 includes a

concavity for mating with the corresponding rod-like stent member 74, as seen in Figure 26. In this manner, each of the cusps 150 and commissures 152 of the valve 40 is securely held in relation to the others, thus facilitating implantation by the surgeon.

5 Details of the commissure legs 356 will now being described with reference to Figures 23 and 26. Each commissure leg 356 extends outward from the handle socket 352 in a generally rectangular cross-section interrupted by an upwardly-facing inner notch 370 oriented cross-wise to the leg. And upwardly-facing radial channel 372 having a depth of approximately half of each
10 commissure leg 356 extends from about the inner notch 370 to the outermost end of the leg. The inner notch 370 is not quite as deep as the channel 372, as seen in Figure 26. The radial channel 372 divides the upper portion of each commissure leg 356 into two walls 374a, 374b. An eyehole 376 is formed in one of the walls 374a, and a corresponding outer notch 378 is formed in the
15 other wall 374b aligned with the eyehole. The outer notch 378 is also not quite as deep as the channel 372.

With reference to Figures 24 and 26, the upper suture 360 is preferably tied to the eyehole 376 in the first wall 374a. The suture 360 then passes across the channel 372, through the outer notch 378, and is passed along the inner
20 notch 370, again traversing the channel 372. The suture 368 is then passed through a suture-permeable portion of the valve commissure 152, such as through the connecting band 48. After passing through the commissure 152, the suture 360 is again looped through one or both of the notches 370, 378 and re-tied to the eyehole 376. By proper threading of the upper suture 360, each
25 commissure 152 can be secured to the commissure leg 356 and easily released by inserting a scalpel blade into the radial channel 372 to sever the portions of the suture therein.

Details of each cusp leg 358 can be seen in Figures 23 and 26. A pair

of longitudinal rails 380a, 380b are provided on the outer side of each cusp leg 358. Toward the lower end of the rails 380a,b, a pair of aligned eyeholes 382 provide anchoring locations for the lower suture 362. A scalpel guide or relief 384 is formed in one of the rails 380b. As seen in Figure 24, the lower suture 362 extends downward from the eyeholes 382, passes through a suture-permeable portion of the cusp 150, and is then returned and secured to the eyeholes 382. The relief 384 exposes a portion of the lower suture 362 for severing by the surgeon using a scalpel blade. It will thus be understood that the holder 350 can be quickly released from the valve 40 by a series of six 5 scalpel strokes, with each of the sutures 360, 362 remaining attached to the holder 350 and being withdrawn from the valve 40 as the holder is withdrawn.

10 Figures 27A and 27B illustrate an alternative holder 390 useful for implanting the flexible heart valve 40 of the present invention. The holder 390 is substantially similar to the holder 350 described above, but the ends of each 15 of a plurality of rigid legs for attaching to the valve cusps are flared, or, more precisely, each lower leg has a width from a hub to a terminal end that is greatest at the terminal end to provide more surface area to contact the corresponding valve cusp. That is, the holder 390 includes a plurality of upper legs 392 having a generally constant width, and a plurality of lower legs 394 having flared ends 396, the legs extending from a central hub 398. Again, the 20 upper legs 392 extend radially outward to connect to the valve commissures 152, and the lower legs 394 angle radially outward and downward to connect to the valve cusps 150. The flared ends 396 impart greater stability to the flexible valve 40 during implantation, especially helping to prevent movement of the 25 cusps 150. In addition, the legs 194 remain fairly narrow until the flared ends 396 to maintain good visibility through the spaces between the plurality of legs. That is, for example, the surgeon can continue to view the valve leaflets 42 between the legs as a check on valve orientation.

Independent Leaflets

A further aspect of the invention is a heart valve having three leaflets directly sutured to the aortic annulus wherein the commissures of adjacent 5 leaflets are totally or partially independent, and may be connected during implant but will become independent thereafter. This gives the independent leaflets and juxtaposed commissures full freedom to move during systole and diastole, thus reducing the pressure gradient. For example, any of the stent assemblies described herein (such as, e.g., the stent assemblies of Figures 17- 10 19) may include separate stent members initially coupled together with a permanent or bioresorbable fastener, the latter dissolving after a fairly short amount of time to permit independent movement of the leaflets. In addition, the present invention discloses an independent leaflet and implantation device that can replace a single defective leaflet, with the prosthetic leaflet functioning in 15 conjunction with the remaining native leaflets.

One example of an independent leaflet 400 seen in Figures 28A and 28B includes a planar or three-dimensional body 402 defined by a coapting edge 404 and a fixation edge 406. The fixation edge 406 includes an arcuate cusp region 408 and a pair of commissure regions 410. The body 402 is attached along its 20 fixation edge 406 to an arcuate flexible support 412 that preserves the shape of the fixation edge and provides a platform for attachment to the native tissue. Figure 28B shows the leaflet 400 attached to a native annulus 422 adjacent a native leaflet 423.

The leaflet body 402 may be made from a biological material such as a 25 porcine valve leaflet or a piece of bovine pericardium, chemically or physically treated to prevent immunological reaction and fatigue. Alternatively, the leaflet body 402 may be formed of a synthetic material such as a polymer or a woven fabric. The flexible support 412 is desirably made of a synthetic material, for

example silicone or PTFE.

As mentioned previously, the independent leaflet 400 may be used with other such leaflets, preferably three total, that are attached directly to an ascending aorta and function together as a prosthetic valve. That is, as seen in 5 Figure 29A, adjacent flexible supports 412 may be attached at their juxtaposed commissure regions with a separate fastener 414, such as a clip.. The clip 414 may be permanent or bioresorbable. Regardless of its longevity, the clips 414, when securing the leaflets 400 together, permit the leaflets to flex with respect to one another so as to allow the assembled valve to move in synch with the 10 native tissue during the systole/diastole cycle. This, in turn, reduces the pressure gradient through the valve. Figure 29B illustrates an alternative fastener between independent leaflets in the form of a continuous scalloped wire or stent 416. Each leaflet 400 (either the leaflet body 402 directly or via the support 412) is attached to the scalloped stent 416 and thus functions together with the 15 other leaflets in a prosthetic valve. The embodiment in Figure 29B is similar to those previously described, wherein the scalloped stent 416 is highly flexible and permits both cusp and commissure movement. Again, however, the commissure regions 418 of the stent 416 may be bioresorbable to result in completely independent leaflets after a period of time in the body.

20 Figure 30 is a perspective view of an exemplary independent leaflet measuring device 420 used to select the appropriate leaflet 400 according to the size and geometry of the native annulus 422. The device 420 includes a handle 424 and an arcuate leaflet sizer 426 that is sized and shaped to match the 25 prosthetic leaflet. Two or more struts 428 may extend between the handle 424 and sizer 426 to improve stability in rotation and manipulation of the sizer.

Figures 31A-31C are schematic views of a device 440 for automatically implanting an independent leaflet of the present invention, illustrating an articulated holder especially suited for minimally invasive environments. The

device 440 includes a handle 442 connected to the independent leaflet 444 via a leaflet holder 446, comprising a plurality of movable struts 446. The struts 446 pivot or slide with respect to one another to convert the device from the low-profile configuration shown in Figure 31A capable of passing through small apertures, to the full deployment configuration of Figure 31C. The leaflet 444 may be attached to the leaflet holder 446 with sutures or the like. A plurality of staples 448 are provided extending outward from the leaflet fixation edge that pierce the native tissue and are deformed by a backing tool or assume a bent shape upon a temperature change. The final configuration is seen in Figure 10 31C, and those of skill in the art will appreciate the ease of use of the separate leaflet implantation procedure. Once implanted, any structure connecting the leaflet 444 to the device 440 is severed, and the device removed.

Figures 32A-32C are schematic views of a still further exemplary implantation device for the independent leaflet embodiment. The device 15 includes an anvil or backing portion 460 having a handle 462 and a plurality of fluid-carrying tubes 464 through which a cold or warm fluid can circulate, as seen by the arrows 466. The circulating fluid regulates the temperature of the tubes 464 during implantation. The device further includes a holder 470, similar to the holder 440 of Figure 31A, to which an independent leaflet 472 is 20 temporarily attached, such as with sutures 474. The fluid-carrying tubes 464 of the backing portion 460 is placed below the native annulus 476 while the leaflet holder 470 is maneuvered into position above the annulus. Opposite displacement of the backing portion 460 and holder 470 causes a plurality of staples 478 to pierce the annulus 476 and be deflected or otherwise curled by the 25 tubes 464. If the staples 478 are shape memory alloy materials like Nitinol, the fluid circulating through the tubes 464 can be used to cause a temperature-induced shape change.

Figure 33 is a cross-sectional view through one embodiment of an

attachment structure for the independent leaflet embodiment. The structure includes staples 480 that extend outward from a leaflet fixation edge 482 through the native tissue 484, and curl or bend into a shape that prevents removal. The curling of the staples 480 may be accomplished using the device 460 (i.e., the backing portion 460 and holder 470) that provide a backing plate or anvil, or through a temperature change, such as when a shape memory material is used. In the illustrated embodiment, the staples 480 may include adjacent legs that curl at different lengths to accommodate one another.

Exemplary dimension are shown in Figure 33, with the width of the leaflet fixation edge 482 being about 9 mm, the length of one leg of each staple 480 being about 8 mm, and the length of one leg of each staple 480 being about 10 mm.

The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. In particular, though the flexible nature of the present heart valve has been described as being particularly suitable for use in the aortic position, the advantage of flexibility could equally apply to a valve implanted in other positions, such as the mitral position. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

WHAT IS CLAIMED IS:

1. A prosthetic heart valve, comprising:
 - a flexible, generally cylindrical stent having alternating cusps and commissures;
 - 5 a plurality of flexible leaflets attached to the stent so as to form a one-way valve within the cylinder; and
 - a flexible band attached along the stent and having a free edge extending outward from the stent along the alternating cusps and commissures for connecting the heart valve to an anatomical orifice.
- 10 2. A highly flexible heart valve, comprising:
 - a stent/leaflet subassembly including a peripheral stent and a plurality of leaflets disposed therewithin, the stent/leaflet subassembly including alternating cusps and commissures; and
 - a connecting band attached to the stent/leaflet subassembly and following the alternating cusps and commissures, the band having a free edge extending from the stent for connecting the heart valve to an anatomical orifice.
- 15 3. The heart valve of either of claims 1 or 2, wherein the stent is configured to permit the cusps and commissures to move radially in and out.
- 20 4. The heart valve of either of claims 1 or 2, wherein the stent comprises a cloth-covered rod-like structure.
- 25 5. The heart valve of claim 4, wherein the cloth-covering closely surrounds the rod-like structure and exhibits a flap projecting outward therefrom substantially the entire length of the cusps and commissures for connecting to the band and leaflets.
6. The heart valve of either of claims 1 or 2, wherein the stent comprises a plurality of separate elements, each having arcuate cusp regions and upstanding commissure regions, wherein each pair of commissure regions of

adjacent elements are juxtaposed to define each commissure.

7. The heart valve of claim 6, wherein each pair of commissure regions of adjacent elements is coupled together to be relatively fixed at the commissures, while the intermediate cusps are permitted to move radially with respect to the commissures.

8. The heart valve of either of claims 1 or 2, wherein the band comprises a suture-permeable inner member and a cloth outer cover, the band exhibiting continuous cusp portions and commissure portions.

9. The heart valve of claim 8, wherein the suture-permeable inner member comprises a molded silicone structure.

10. The heart valve of claim 8, wherein the band comprises an outwardly projecting series of parallel ribs extending continuously along the entire band cusp portions and commissure portions.

11. The heart valve of claim 8, wherein the commissure portions of the band are generally planar and axially aligned, and the cusp portions of the band each include an outwardly angled portion and an inwardly angled ledge.

12. The heart valve of claim 11, wherein the inwardly angled ledge of each cusp portion of the band extends inward a distance sufficient to support the corresponding cusp.

13. The heart valve of either of claims 1 or 2, wherein the band includes arcuate cusp portions generally conforming to the cusps, and the band includes commissure portions therebetween each having an inverted U-shape to define a downwardly opening gap that enhances flexibility of the valve by permitting relative cusp movement.

25

14. A prosthetic heart valve, comprising:

a plurality of flexible leaflets each having an arcuate cusp edge and a coapting edge; and

a stent including a plurality of cusps connected to each other at upstanding commissures to generally define a substantially cylindrical volume therebetween, the leaflets being attached to the stent within the volume and the cusps being free to move with respect to one another about the commissures.

5

15. The heart valve of claim 14, wherein the stent comprises a plurality of separate members dispose generally in a circle to define the cylindrical volume, each member including an arcuate cusp portion and two upstanding commissure portions, wherein each pair of commissure portions of adjacent members is juxtaposed to define each stent commissure.

10

16. The heart valve of claim 14, wherein the cusps of the valve are hingedly connected to each other.

15

17. The heart valve of claim 16, wherein the stent comprises a single member and the cusps are hingedly connected to each other at coil springs.

18.

The heart valve of claim 16, wherein the stent comprises a plurality of separate members dispose generally in a circle to define the cylindrical volume, each member including an arcuate cusp portion and two upstanding commissure portions, wherein each pair of commissure portions of adjacent members is juxtaposed to define each stent commissure.

20

19. The heart valve of claim 18, wherein each pair of commissure portions is connected with sutures to enable relative movement of adjacent cusp portions.

20

20. The heart valve of claim 18, wherein each commissure portion is connected to pivot about a first axis which is fixed with respect to a second axis about which the adjacent commissure portion pivots.

25

21. The heart valve of claim 20, wherein the first and second axes are coincident.

22. The heart valve of claim 21, wherein each commissure portion

terminates at an arcuate tip, the valve further including coupling members having an arcuate channel therein, the coupling members receiving the arcuate tips of the commissure portions and permitting relative sliding movement about a pivot axis defined by the arcuate channel.

5 23. The heart valve of claim 20, wherein each commissure portion terminates at a generally circular tip, the valve further including coupling members having a pair of spaced pins provided thereon that defined the first and second axes and about which the circular tips of each commissure portion pivot.

10 24. The heart valve of claim 18, wherein the valve includes a plurality of pliable coupling members each of which couples to a pair of adjacent commissure portions to permit relative movement therebetween.

25 25. The heart valve of claim 24, wherein each commissure portion terminates at a generally linear tip, the pliable coupling members comprising pliable tubular sleeves closely fitting over the linear tips.

15 26. The heart valve of Claim 14, further including means for connecting the stent cusps together at the stent commissures to enable relative movement of adjacent cusps.

27. The heart valve of Claim 26, wherein the means for connecting the stent cusps together comprises sutures.

20 28. The heart valve of Claim 26, wherein the means for connecting the stent cusps together comprises a flexible material interface.

29. The heart valve of Claim 26, where the means for connecting the stent cusps together comprises a bioresorbable structure.

30. The heart valve of claim 14, wherein the stent comprises a cloth-covered rod-like structure.

25 31. The heart valve of claim 30, wherein the cloth-covering closely surrounds the rod-like structure and exhibits a flap projecting outward therefrom substantially the entire length of the cusps and commissures.

32. The heart valve of claim 31, wherein the flap has a width that varies along the cusps and commissures of the stent, the flap being narrower in the cusps.

5 33. The heart valve of claim 31, further including a flexible band attached along the stent flap and having a free edge extending outward from the stent along the alternating cusps and commissures for connecting the heart valve to an anatomical orifice.

34. The heart valve of claim 33, wherein the cusp edges of the leaflets are attached between the band and the stent flap.

10 35. The heart valve of claim 33, wherein the band exhibits continuous cusps and commissures, the cusps of the band each including an outwardly angled portion and an inwardly angled ledge extending inward a distance sufficient to support the corresponding cusp of the stent.

15 36. The heart valve of claim 30, wherein the rod-like structure is made of a polymer.

37. The heart valve of claim 22, wherein each separate member is separately cloth-covered.

20 38. The heart valve of claim 37, wherein each upstanding commissure portion terminates in a substantially circular bent tip, adjacent and bent tips of each separate member being juxtaposed and sutured together through the respective cloth coverings.

25 39. The heart valve of claim 18, wherein each leaflet includes an arcuate cusp edge terminating at outer tips joined to the stent commissures, and a coapting edge that is defined by two relatively angled lines joined at an apex midway between the two tips.

40. The heart valve of claim 39, wherein each leaflet is made of pericardial tissue.

41. The heart valve of claim 39, wherein the arcuate cusp edges

gradually become asymptotic at the tips.

42. The heart valve of claim 39, further including an outwardly angled transition edge from the arcuate cusp edges to the tips.

43. The heart valve of claim 42, wherein a generally linear edge is defined between each outwardly angled transition edge and the corresponding tip defining a generally trapezoidal tab adjacent the tips.

44. The heart valve of claim 18, wherein each leaflet includes an arcuate cusp edge terminating at outer tips joined to the stent commissures, wherein adjacent tips are joined not to each other but to portions of the stent that are permitted to move with respect to one another.

45. The heart valve of claim 44, further including a flexible band attached along the stent and having a free edge extending outward from the stent along the alternating cusps and commissures for connecting the heart valve to an anatomical orifice, the band defining an inverted U-shape at the stent commissures with a gap formed between portions of the stent that are permitted to move with respect to one another.

46. A prosthetic heart valve, comprising:
a stent including a plurality of stent members adjacently disposed around a circle to define a substantially cylindrical volume therebetween,
the stent including a plurality of alternating cusps and commissures.

47. The heart valve of claim 46, wherein each stent member includes an arcuate cusp region and two upstanding commissure regions, and wherein each pair of commissure regions of adjacent stent members is juxtaposed to define each stent commissure.

48. The heart valve of Claim 47, further including means for connecting the stent members together at the stent commissures to enable relative movement of adjacent cusp regions.

49. The heart valve of Claim 48, wherein the means for connecting the stent members together comprises sutures.

50. The heart valve of Claim 48, wherein the means for connecting the stent members together comprises a flexible material interface.

51. The heart valve of Claim 48, where the means for connecting the stent members together comprises a bioresorbable structure.

52. The heart valve of claim 47, wherein each commissure region is connected to pivot about a first axis which is fixed with respect to a second axis about which the adjacent commissure region pivots.

10 53. The heart valve of claim 52, wherein each commissure region terminates at a generally circular tip, the valve further including coupling members having a pair of spaced pins provided thereon that defined the first and second axes and about which the circular tips of each commissure region pivot.

15 54. The heart valve of claim 52, wherein the first and second axes are coincident.

20 55. The heart valve of claim 47, wherein each commissure region terminates at an arcuate tip, the valve further including coupling members having an arcuate channel therein, the coupling members receiving the arcuate tips of the commissure regions and permitting relative sliding movement about a pivot axis defined by the arcuate channel.

56. The heart valve of claim 47, wherein the valve includes a plurality of pliable coupling members each of which couples to a pair of adjacent commissure regions to permit relative movement therebetween.

25 57. The heart valve of claim 56, wherein each commissure region terminates at a generally linear tip, the pliable coupling members comprising pliable tubular sleeves closely fitting over the linear tips.

58. The heart valve of claim 46, wherein each stent member is coupled to move with respect to the other stent members about the stent

commissures.

59. The heart valve of claim 58, wherein each stent member is pivotally coupled with respect to the other stent members at the stent commissures.

5 60. The heart valve of claim 58, wherein each stent member is flexibly coupled with respect to the other stent members at the stent commissures.

10 61. The heart valve of claim 60, wherein each stent member is elastically coupled with respect to the other stent members at the stent commissures.

15 62. A holder for a prosthetic heart valve, comprising:
a central hub with a plurality of radially outward upper legs, and a
plurality of lower legs angled downward and outward, the upper legs
being adapted to connect to corresponding commissures of a prosthetic
heart valve, and the lower legs being adapted to connect to corresponding
cusps of the prosthetic heart valve.

63. The holder of claim 62, wherein the hub is internally threaded for mating with a handle.

20 64. The holder of claim 62, wherein each of the upper and lower legs includes structure to which sutures can be anchored.

65. The holder of claim 62, wherein each lower leg has a width from the hub to a terminal end that is greatest at the terminal end to provide more surface area to contact the corresponding valve cusp.

25

66. A prosthetic heart valve and implantation holder combination,
comprising:
a flexible prosthetic heart valve having alternating cusps and

commissures in a generally cylindrical configuration and adapted to move radially in and out with respect to one another; and

the rigid holder having structure for maintaining a fixed shape of the flexible prosthetic heart valve during implantation.

5 67. The combination of claim 66, wherein the holder includes a central hub with a plurality of radially outward upper legs, and a plurality of lower legs angled downward and outward, the upper legs being adapted to connect to corresponding commissures of the prosthetic heart valve, and the lower legs being adapted to connect to corresponding cusps of the prosthetic
10 heart valve.

68. The combination of claim 67, wherein the hub is internally threaded for mating with a handle.

15 69. The combination of claim 66, structure on the holder for maintaining the fixed shape of the heart valve comprises a plurality of outwardly extending legs, the assembly further comprising a plurality of sutures attaching each leg to a portion on the heart valve.

70. The combination of claim 69, wherein each of the legs includes structure to which sutures can be anchored.

20 71. The combination of claim 69, wherein the holder includes one leg for each cusp and one leg for each commissure of the valve.

72. A heart valve leaflet, comprising:

a flexible, planar body having an arcuate cusp edge terminating at outer tips, and a coapting edge that is defined by two relatively angled lines joined at an apex directed away from the cusp edge midway between the two tips.

25 73. The heart valve of claim 72, wherein each leaflet is made of pericardial tissue.

74. The heart valve of claim 72, wherein the arcuate cusp edges gradually become asymptotic at the tips.

75. The heart valve of claim 72, further including an outwardly angled transition edge from the arcuate cusp edges to the tips.

5 76. The heart valve of claim 75, wherein a generally linear edge is defined between each outwardly angled transition edge and the corresponding tip defining a generally trapezoidal tab adjacent the tips.

77. An independent heart valve leaflet, comprising:

10 a flexible body having an arcuate fixation edge defined by a cusp region and two commissure regions, and a coapting edge between the two commissure regions, and a flexible support attached along the fixation edge.

78. The leaflet of claim 77, wherein the flexible body is a
15 biomaterial and the support comprises a strip of synthetic material.

79. The leaflet of claim 78, wherein the flexible body is made of bovine pericardium.

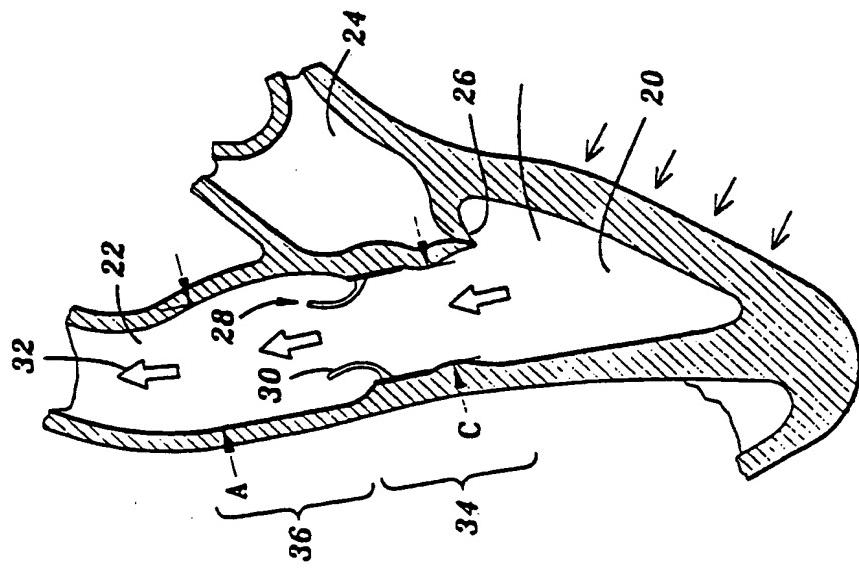
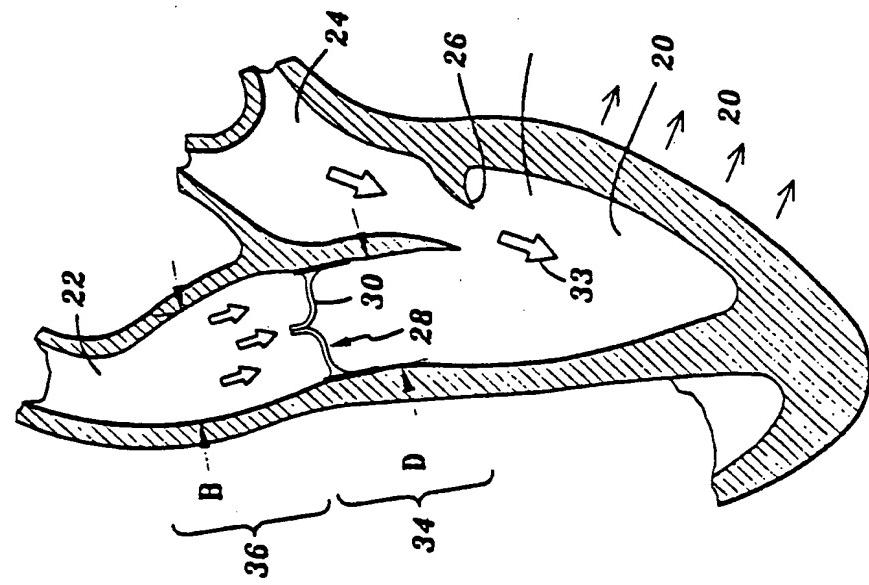
Fig. 1*Fig. 2*

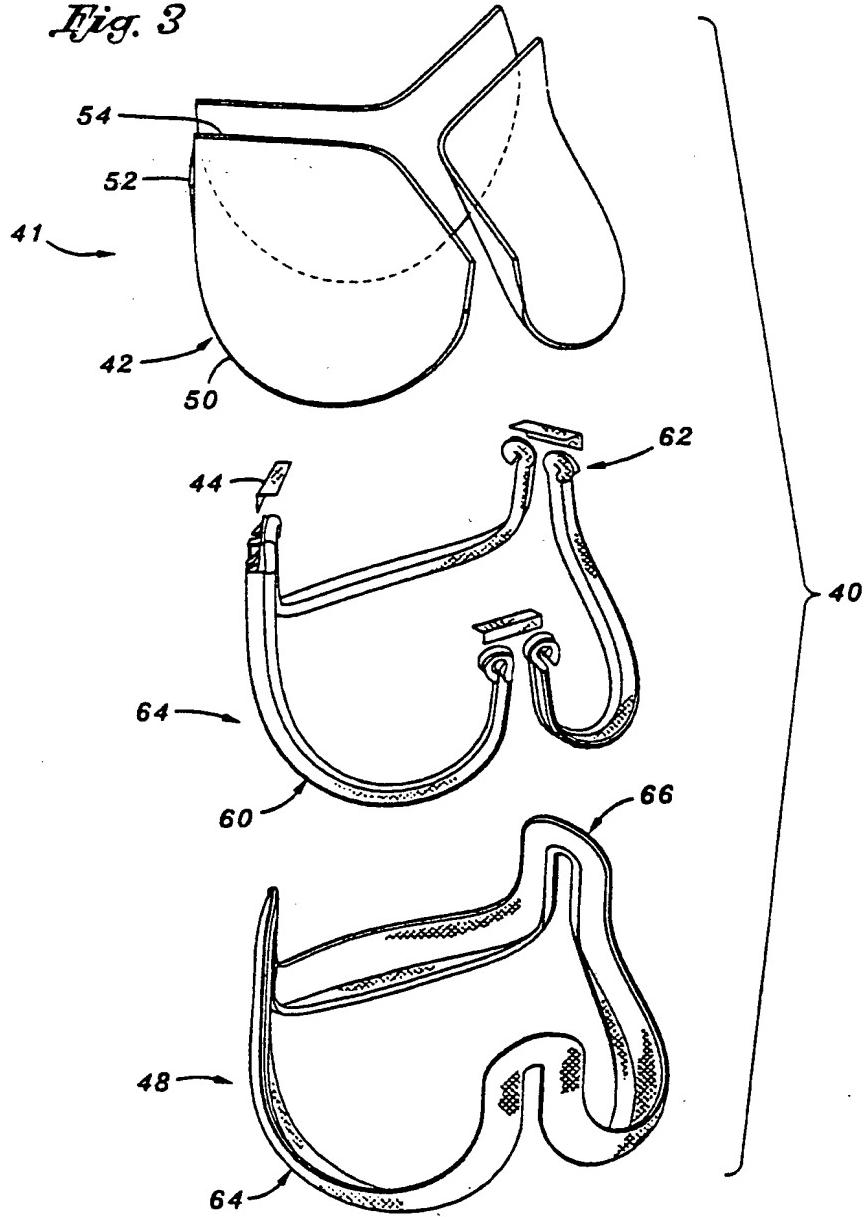
Fig. 3

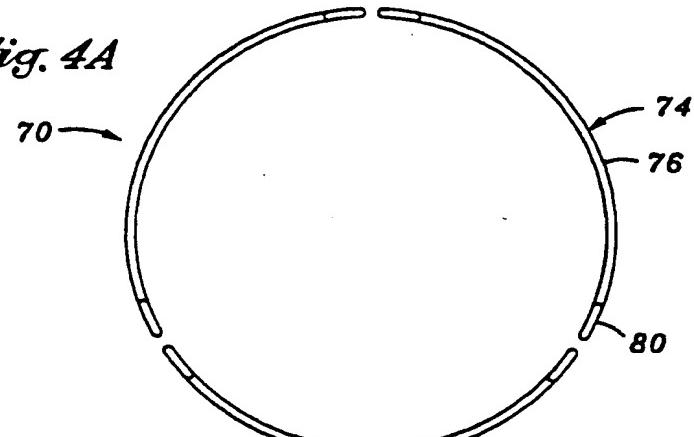
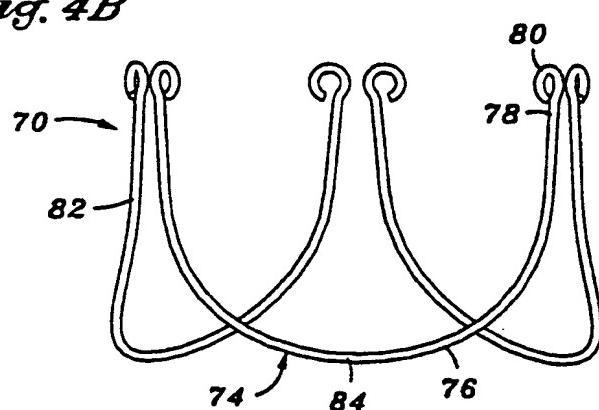
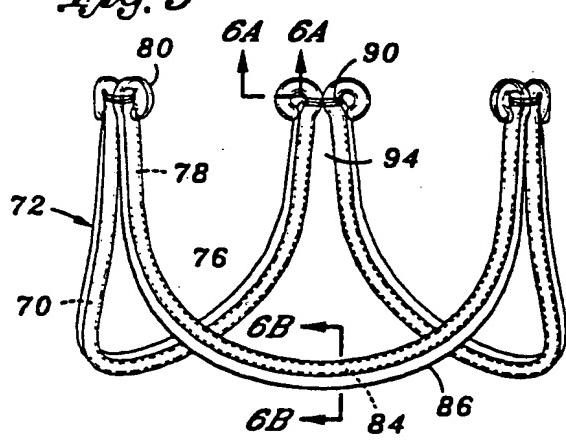
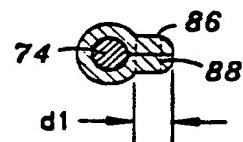
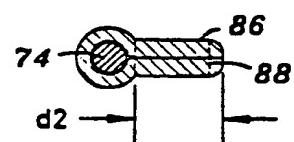
Fig. 4A*Fig. 4B**Fig. 5**Fig. 6A**Fig. 6B*

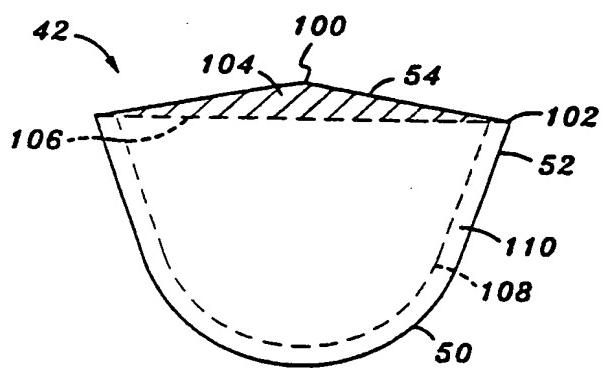
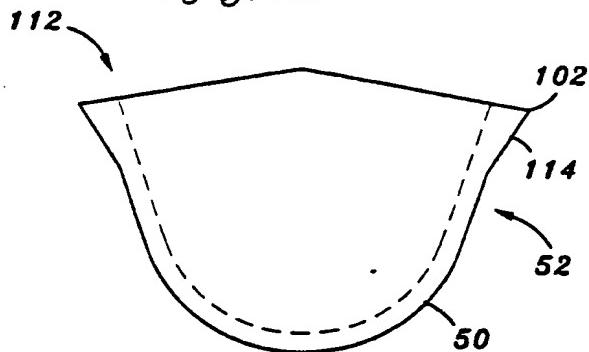
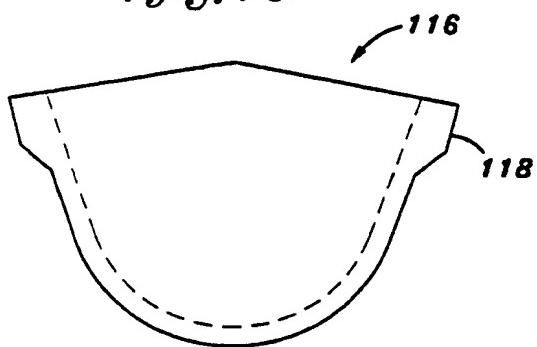
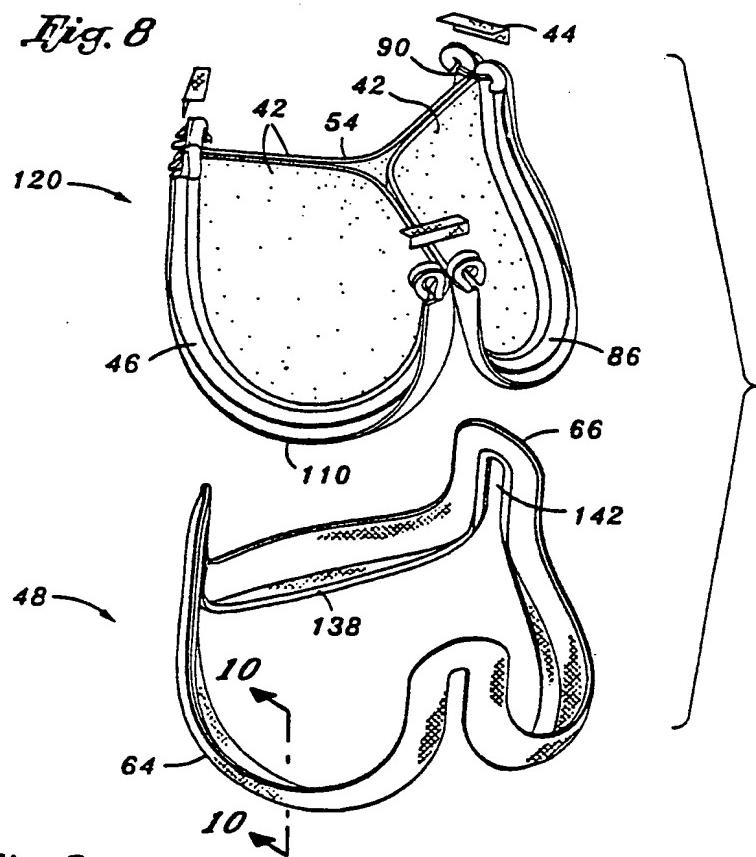
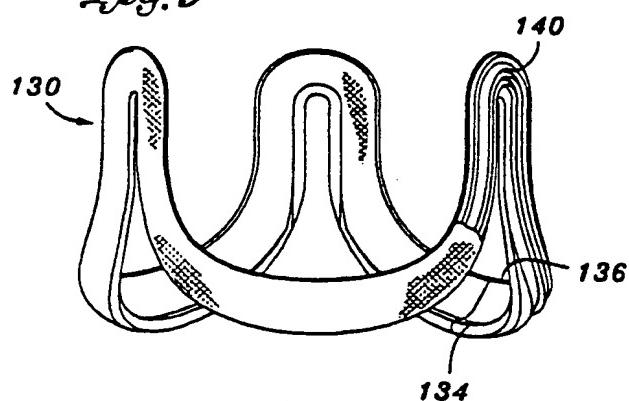
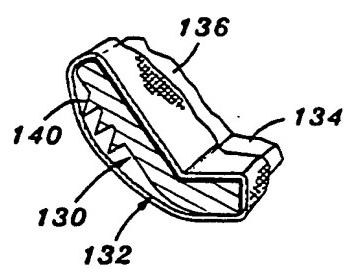
Fig. 7A*Fig. 7B**Fig. 7C*

Fig. 8*Fig. 9**Fig. 10*

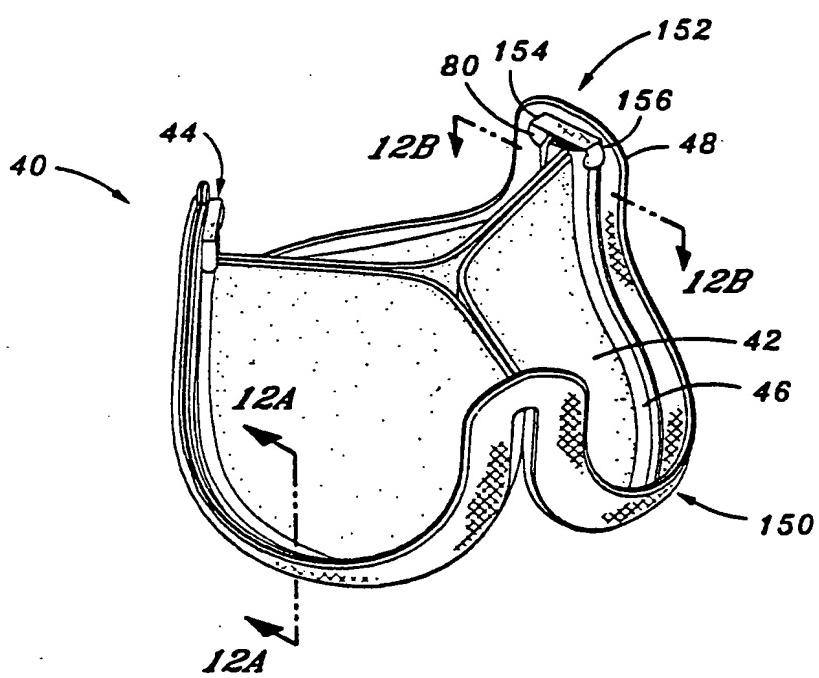
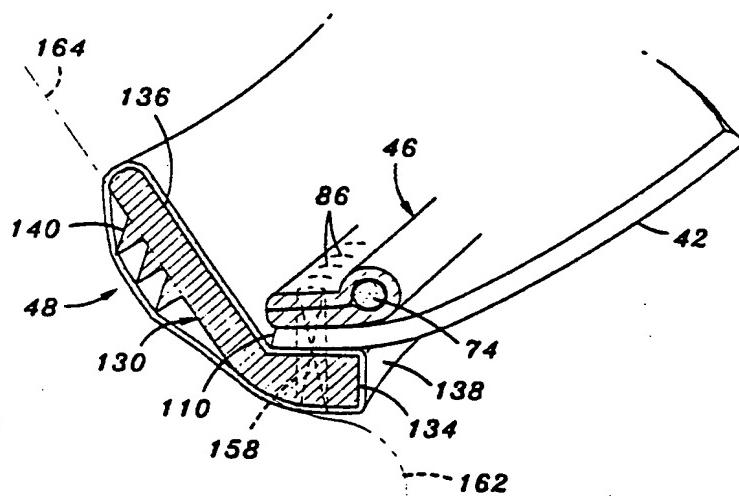
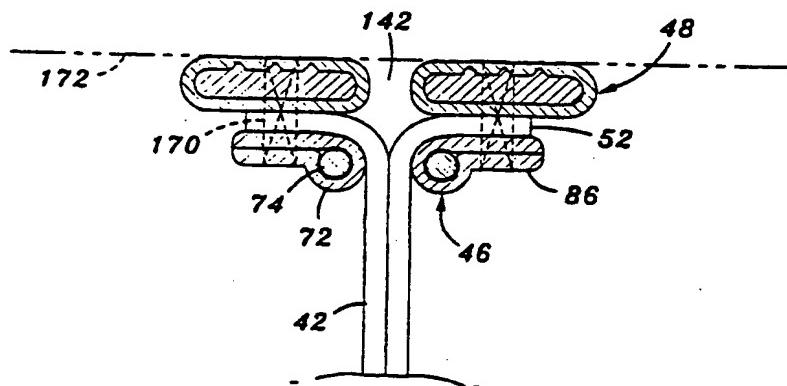


Fig. 11

Fig. 12A*Fig. 12B*

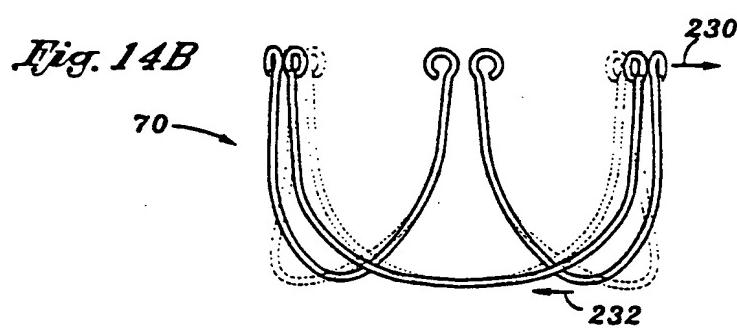
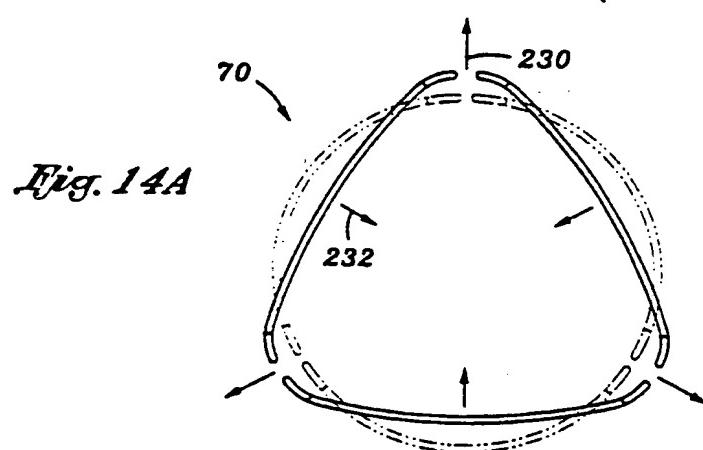
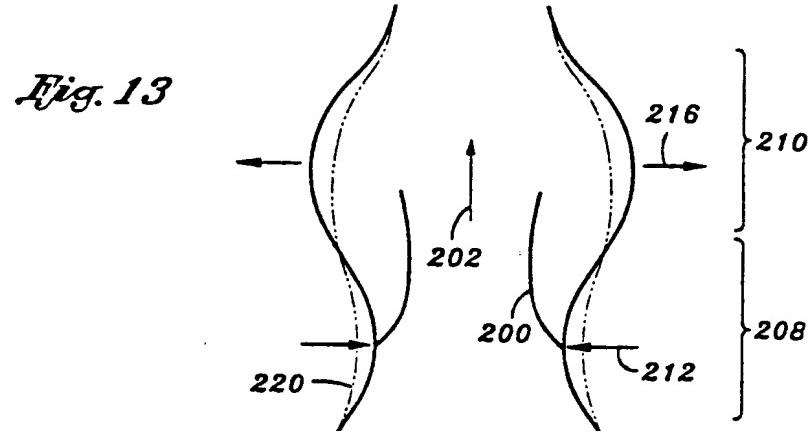


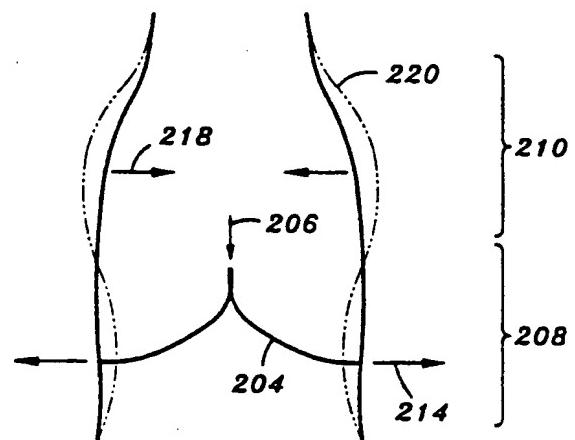
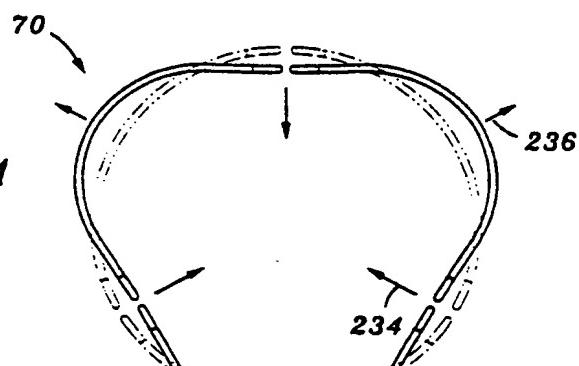
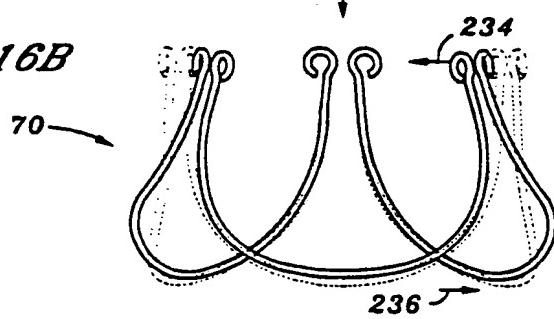
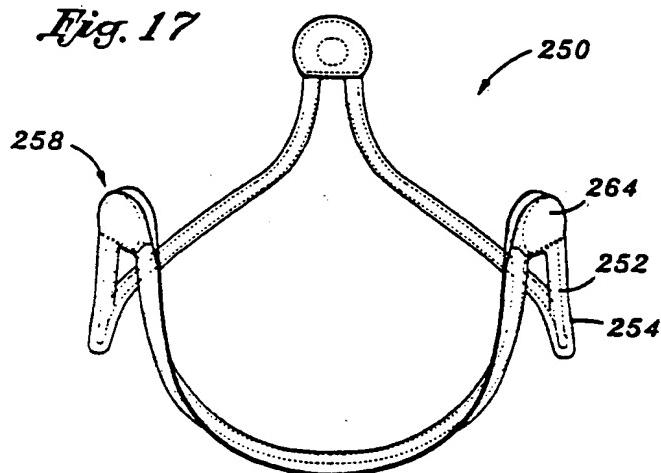
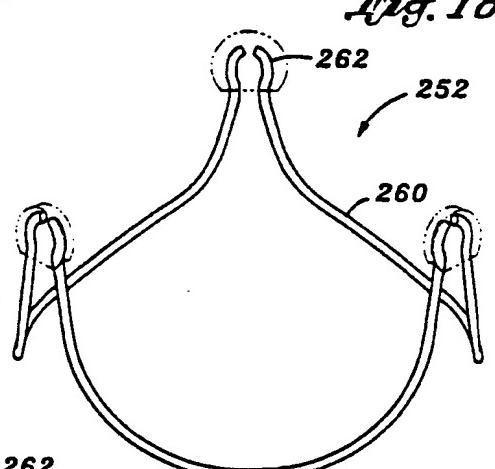
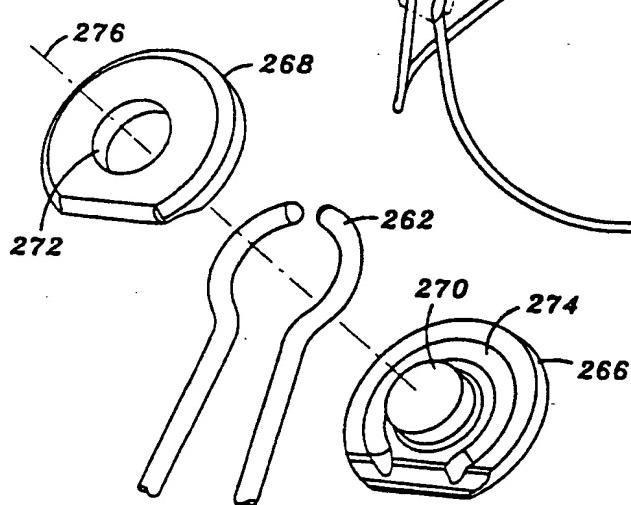
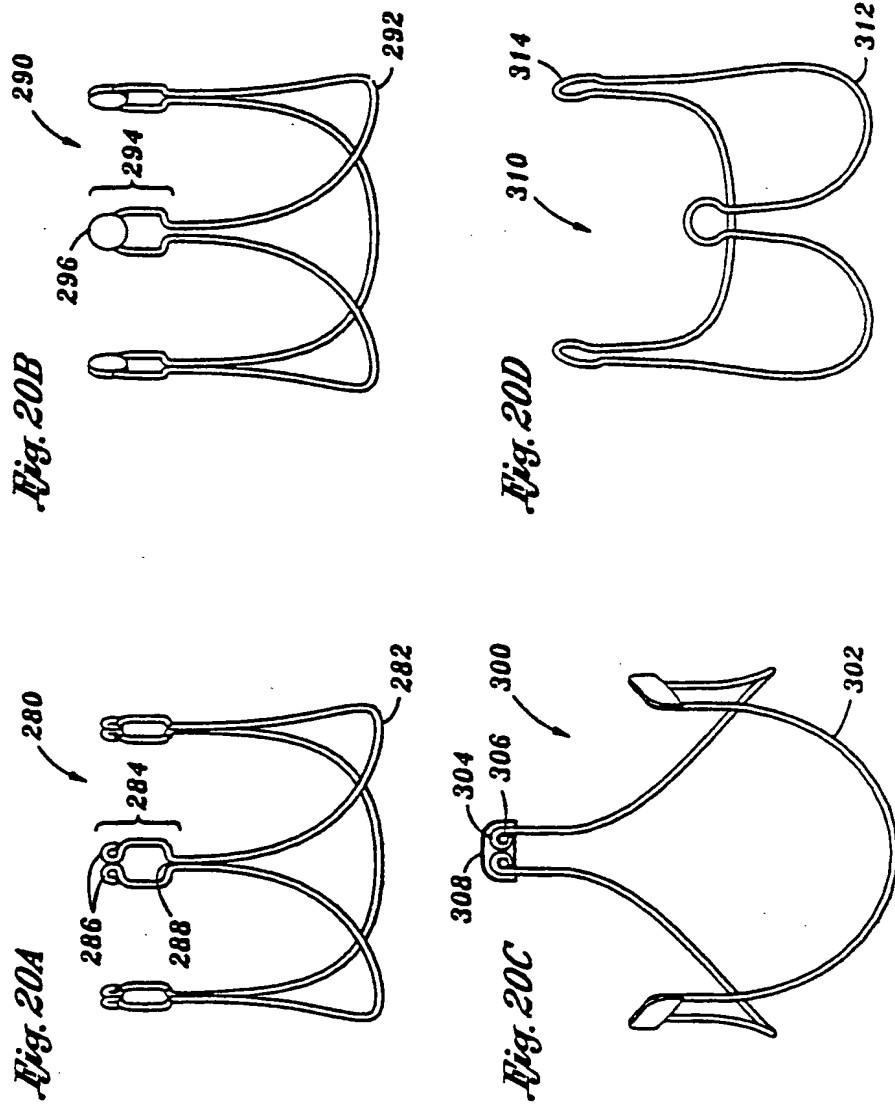
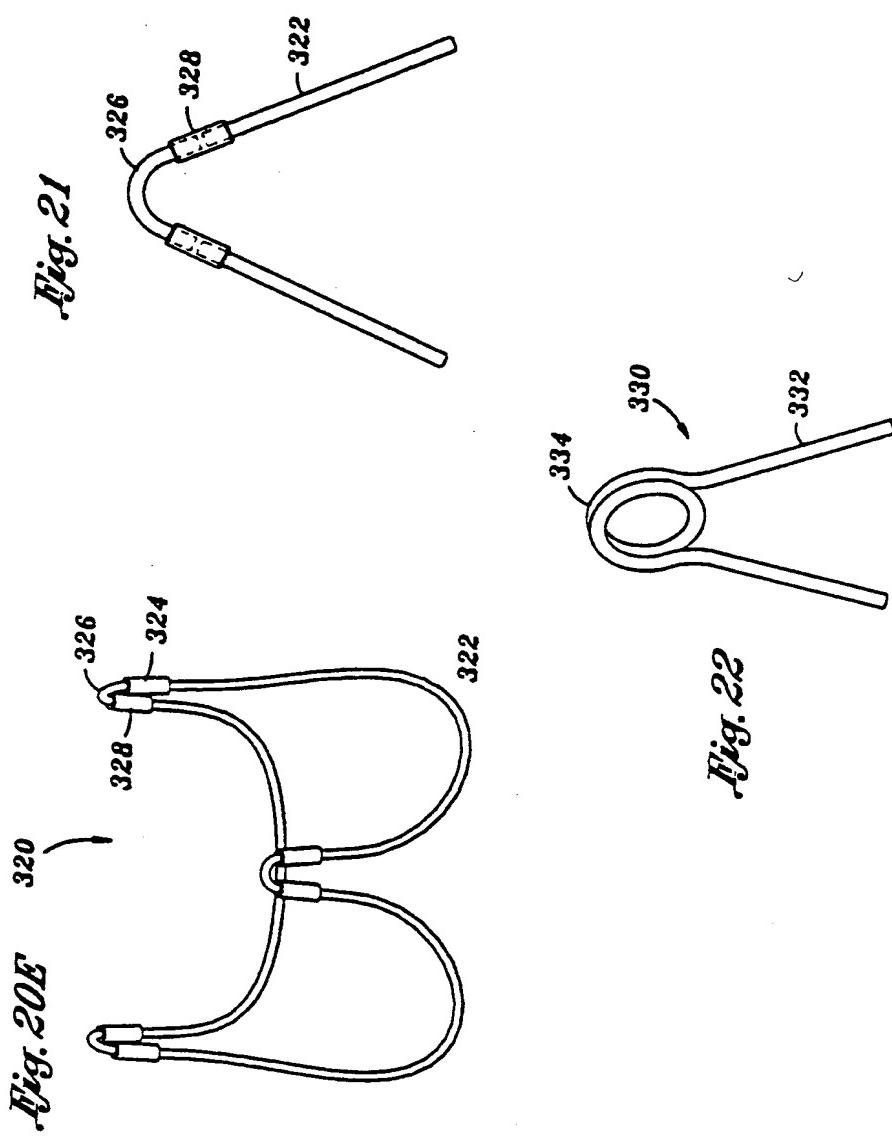
Fig. 15*Fig. 16A**Fig. 16B*

Fig. 17*Fig. 18**Fig. 19*





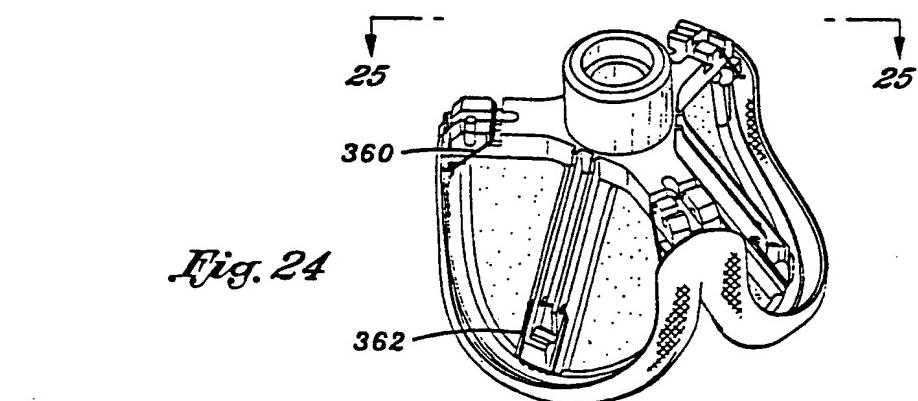
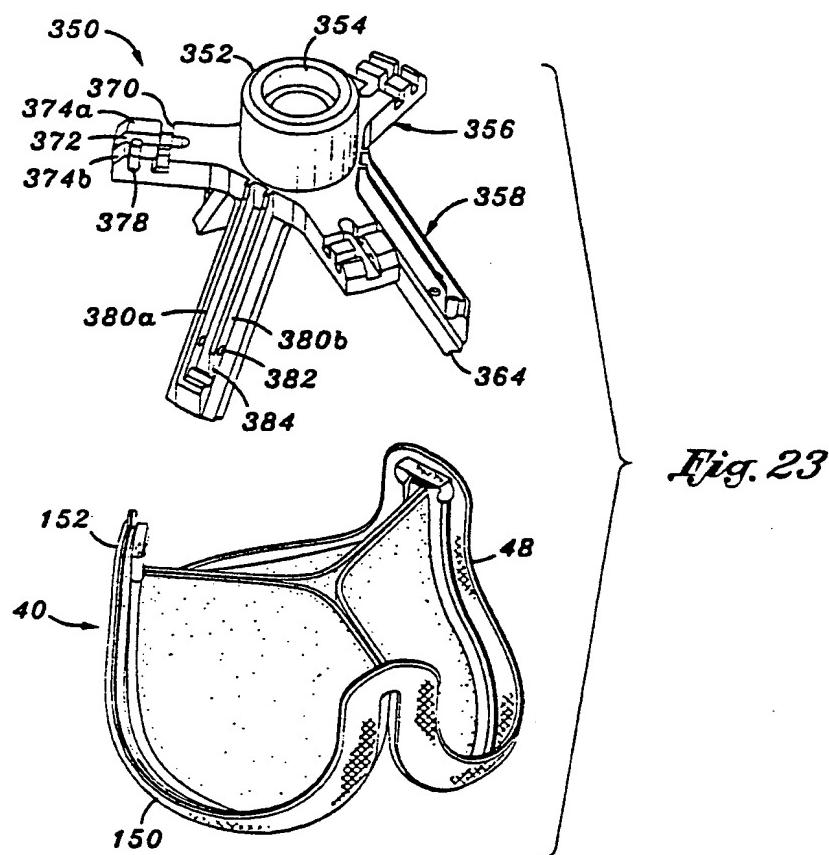
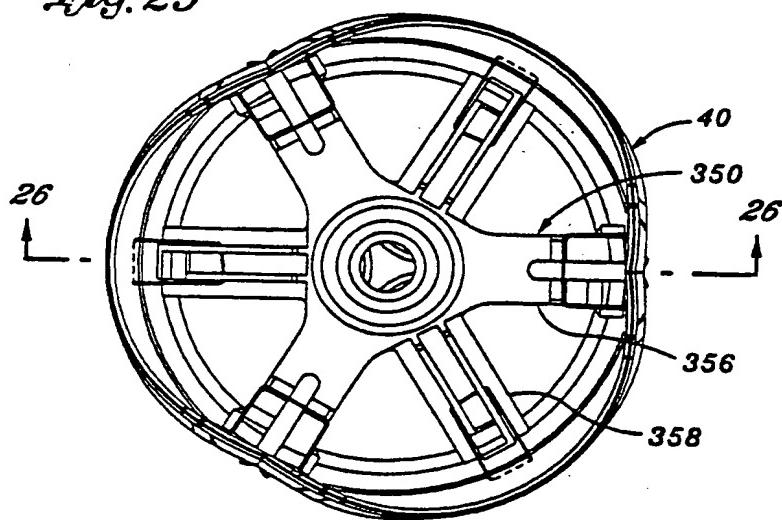
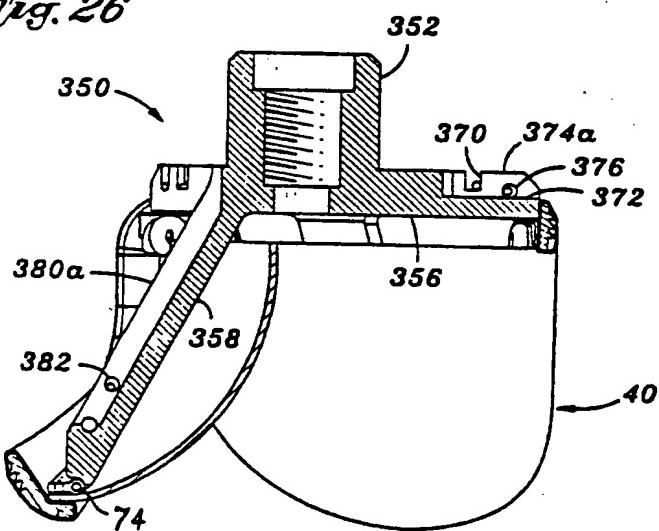
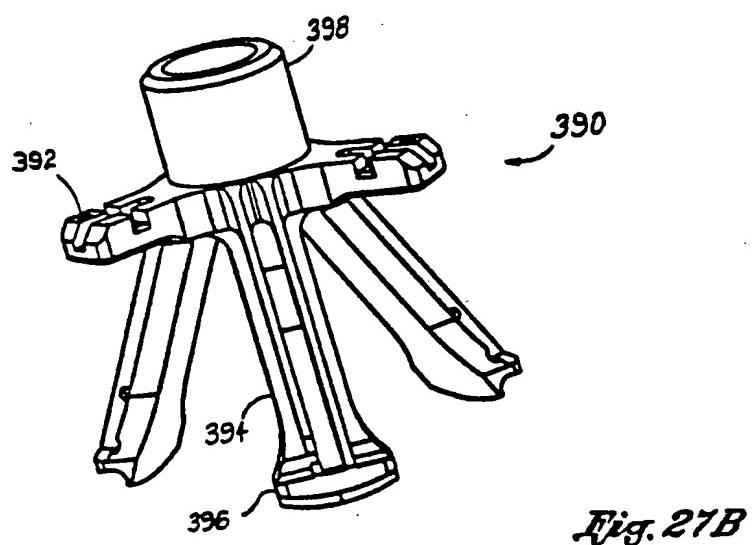
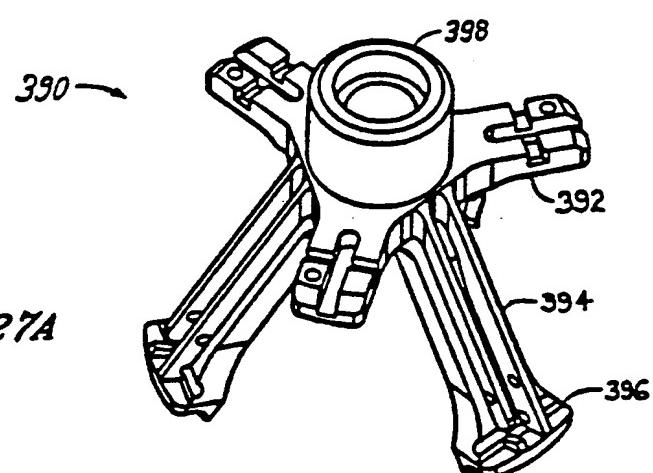


Fig. 25*Fig. 26*



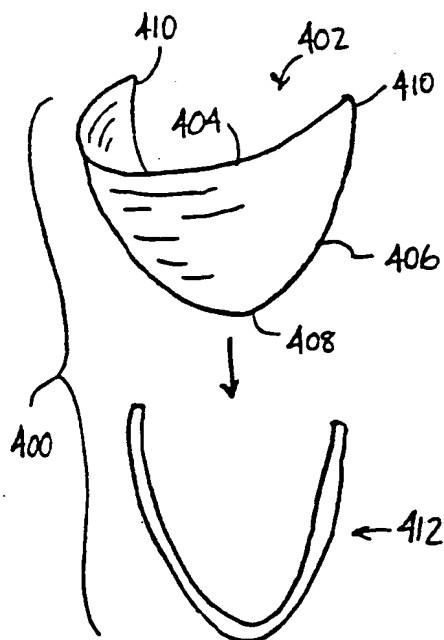


Fig. 28A

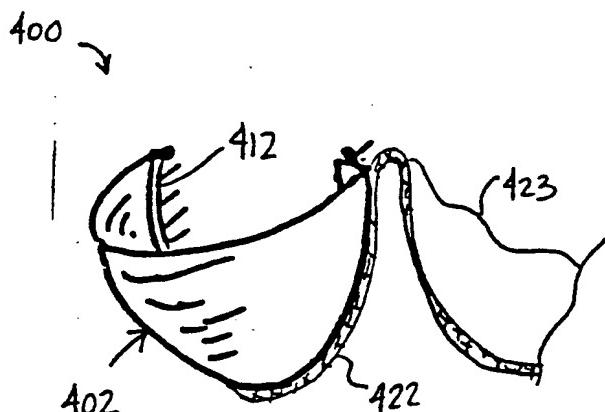


Fig. 28B

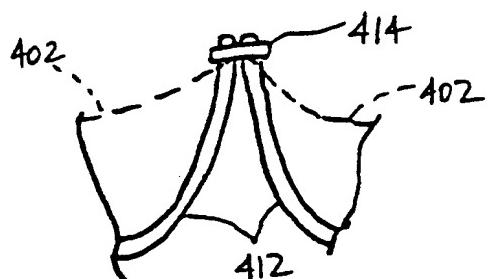


Fig. 29A

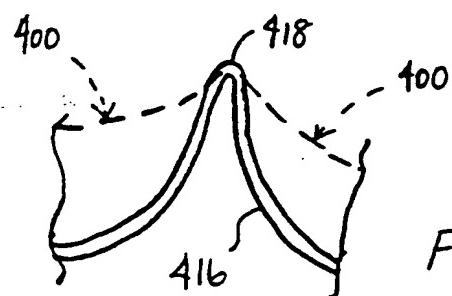


Fig. 29B

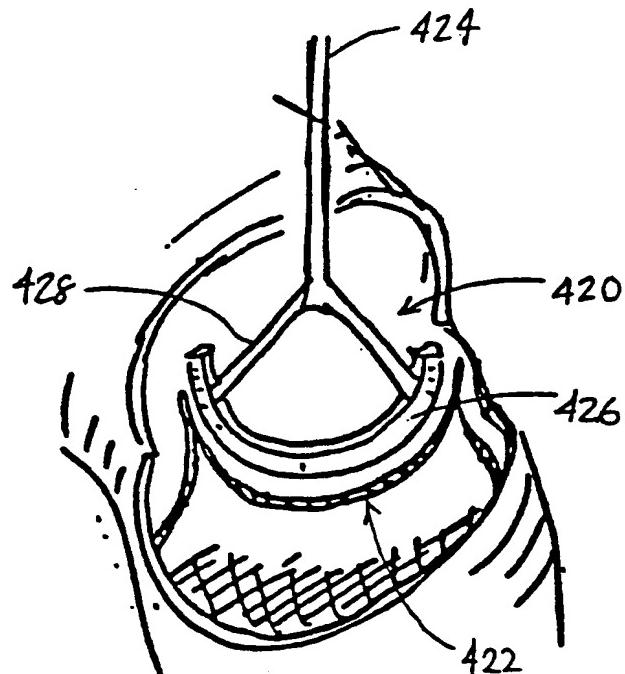


Fig. 30

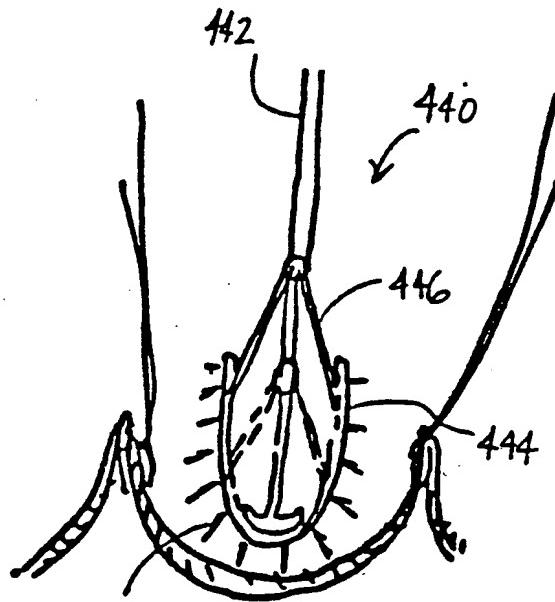


Fig. 31A

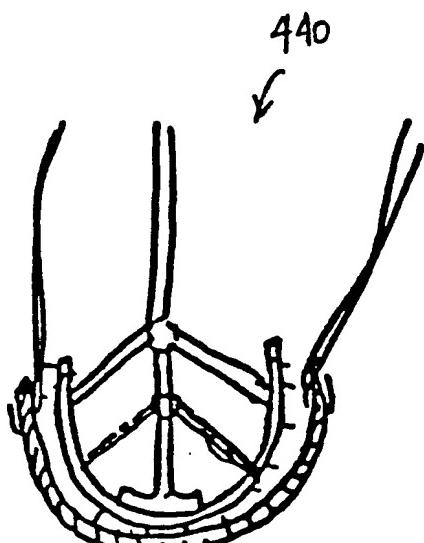


Fig. 31B

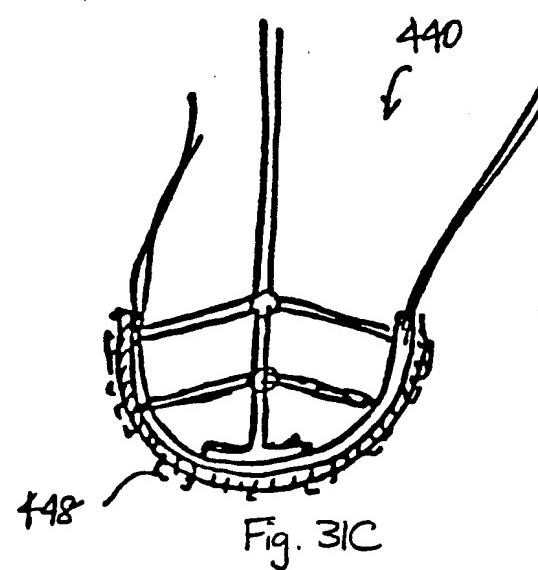


Fig. 31C

